

NATIONAL CANCER INSTITUTE COMMUNITY ONCOLOGY RESEARCH PROGRAM GUIDELINES

DIVISION OF CANCER PREVENTION

NATIONAL CANCER INSTITUTE

NATIONAL INSTITUTES OF HEALTH

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Part 1: Overview of the National Cancer Institute Community Oncology Research Program (NCORP)

I. Introduction

A. Purpose and Content of Guidelines

These Guidelines for the National Cancer Institute Community Oncology Research Program (NCORP) have been developed by staff of the Division of Cancer Prevention (DCP) and the Division of Cancer Control and Population Sciences (DCCPS), NCI. Because NCORP is an integral part of the overall National Clinical Trials Network (NCTN), these NCORP Guidelines have been developed in collaboration with staff of the Division of Cancer Treatment and Diagnosis, Cancer Therapy Evaluation Program (DCTD/CTEP). DCP and DCCPS have also collaborated in the creation of these Guidelines with the Center to Reduce Cancer Health Disparities (CRCHD), the Office of Grants Administration (OGA) and the NCI Division of Extramural Activities (DEA), as well as with the advice of members of the extramural scientific community. The purpose of these Guidelines is to describe the NCI's goals and expectations for the various applicants and investigators, peer reviewers, and the National Institutes of Health (NIH) staff who are involved with NCORP. They are intended to encourage a multi-disciplinary, comprehensive, community-based network that will: 1) design and conduct cancer prevention, control, and screening/post-treatment surveillance trials and health-related quality of life (HRQOL) studies embedded in treatment and imaging trials; 2) design and conduct cancer care delivery research studies; and 3) enhance patient and provider access to cancer treatment and imaging trials conducted under the reorganized NCTN; and 4) integrate disparity research questions into clinical trials and cancer care delivery research.

Note: The information provided in the guidance on budget calculations are guidelines and do not reflect a cap on costs that may be requested. Applicants should submit a budget that reflects the scope of work proposed. In addition, there is no requirement to use the sample guidance provided in the NCORP Program Guidelines nor is there any upper limit (i.e., budget cap) on clinical trials infrastructure or cancer care delivery.

Note: The NCTN structures are evolving from the current main clinical trials program, the NCI Clinical Trials Cooperative Groups. Because not all awards for the NCTN components may be in place at the time of NCORP application submission, the further text related to FOA requirements provides dual references, e.g., "Clinical Trials Cooperative Groups or NCTN Operations Centers".

This Guidelines document is divided into four parts as described below:

- **Part 1 – Overview of NCORP**

This part describes NCORP and its policies and procedures, including the Terms and Conditions of Award. Separate sections are devoted to cancer prevention, control and screening/post-treatment

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surveillance and cancer care delivery research, the two main research components comprising the program.

- **Part 2 – Guidelines for Submission of New Applications & Description of Review Process**

This part describes the application, budgetary issues, and peer review processes for new applications.

Note: The information provided in the guidance on budget calculations are guidelines and do NOT reflect a cap on costs that may be requested. Applicants should submit a budget that reflects the scope of work proposed. There is no requirement to use the sample guidance, it is provided as an example.

- **Part 3 – Guidelines for Submission of Continuing Applications**

This part describes the application and budgetary issues for non-competing continuation applications.

- **Part 4 – Appendices**

This part contains appendices relevant to the policies and procedures associated with NCORP and with the application and review processes.

A variety of other rules and regulations affect NCORP (e.g., NIH grants policy, policies of the Office of Human Research Protections). Guidelines in this document are intended to cover NCI/DCP's special requirements for NCORP and to supplement NIH and U.S. Department of Health and Human Services (DHHS) policies. These Guidelines, as well as the policies of all

awardees under NCORP, must adhere to NCI, NIH, and DHHS policies. Applicants should contact the NCORP Director or Associate Director if they believe these Guidelines conflict with other applicable Federal policies in order to resolve any apparent discrepancies in the interpretation of these Guidelines.

B. Background, Overview, and Purpose of NCORP

Although cancer clinical research has traditionally been conducted at academic medical centers, the bulk of cancer care takes place in the community setting. Expanding clinical research beyond the academic environment allows access to a larger and more diverse patient population treated in a variety of “real-world” healthcare delivery settings, which can accelerate accrual to clinical trials, allow for feasibility testing of promising new interventions in variable care environments, and increase the generalizability and relevance of study findings. Engaging community oncologists in collaborative research can also facilitate the uptake of effective, evidence-based practices into routine care.

In recognition of the importance of community-based clinical research, three decades ago, the NCI launched the Community Clinical Oncology Program (CCOPs, MB-CCOPs and CCOP Research Bases) to form a clinical trials network to expand patient and physician access to cutting-edge cancer treatment trials outside of traditional academic medical settings, as well as develop multi-institutional cancer prevention, control and screening/post-treatment surveillance trials and HRQOL studies embedded in treatment and imaging trials. In the years since, the CCOP network has become a key component of the national cancer clinical trials enterprise, contributing a substantial proportion of accrual to phase 2 and 3 treatment and imaging trials with significant representation of minority patients, and implementing a series of pivotal and influential multi-institutional trials in cancer prevention, control and screening/post-treatment surveillance as well as health-related quality of life (HRQOL) studies. In 2007, the NCI’s Community Cancer Centers Program (NCCCCP) was initiated to explore ways in which community hospitals could enhance access to care, improve the quality of care, and expand research across the entire cancer continuum with a focus on diverse racial, ethnic and underserved populations.

Strong clinical trial programs remain essential to achieving the advances required to address the many unmet needs in cancer prevention, control, screening/post-treatment surveillance, post-treatment surveillance and treatment. Yet findings from health services research and the promising role of quality improvement initiatives underscore the critical, complementary role of care delivery structures, processes and organizational policies as determinants of patient care experiences and outcomes. Systematic study and improvement of these factors are important in assuring that all patients, especially those from minority/underserved populations, benefit from the best available knowledge about cancer prevention, control, screening/post-treatment surveillance and treatment.

The importance and influence of cancer care delivery research on patient care has led to the emergence of cancer care delivery as a multidisciplinary field of scientific investigation that studies how complex, multi-level forces, including social factors, financing systems, organizational structures and processes, health technologies, provider and individual behaviors affect cancer outcomes, access to cancer care, the quality and cost of cancer care and ultimately the health and well-being of cancer patients. Its focus includes individuals, families, organizations, institutions, providers, communities, populations and their interactions. As the bulk of cancer care occurs in a community setting, community-based care organizations must be a key focus of cancer care delivery research that seeks to understand and improve patient outcomes based on these factors.

C. Goal, Scope and Strategy of NCORP

NCORP, while maintaining a vigorous program for the design and conduct of cancer prevention, control and screening/post-treatment surveillance trials and HRQOL studies and participation in NCTN treatment and imaging trials, will expand the scope of activity to include cancer care delivery research addressing key questions about multi-level factors that affect access to and quality of care in the community and also increase the focus on minority/underserved populations that are underrepresented in clinical trials and for which cancer care delivery issues are of great importance.

During the start-up and initial phase of NCORP the expected relative balance in level of effort between clinical trials and cancer care delivery research will be approximately 90% and 10%, respectively, for a given Research Base, and this is reflected in the FOA funding estimates. However, funding from other sources can be used to augment the cancer care delivery research efforts.

The overall goal of NCORP is to bring cancer prevention, control, screening/post-treatment surveillance, treatment, and imaging trials, as well as HRQOL and cancer care delivery research studies, to individuals in their own communities, thereby generating a broadly applicable evidence base that contributes to improved patient outcomes and a reduction in cancer disparities.

To address these goals, NCORP will focus on the following activities:

- Implementing an integrated national network of community organizations and Research Bases that will: 1) design and conduct cancer prevention, control and screening/post-treatment surveillance/post-treatment surveillance clinical trials and HRQOL studies embedded in treatment and imaging trials; 2) design and conduct multi-level cancer care delivery research ; and 3) enhance patient and provider access to treatment and imaging trials conducted under the reorganized NCTN
- Facilitating the participation of minorities and other underserved populations across all study types and settings

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- Increasing the integration of health disparities questions across all study types and settings
- Integrating the expertise of primary health care providers, other specialists and health services and behavioral researchers with oncologists, especially as they relate to transitions in care
- Accelerating the translation of knowledge gained from cancer clinical trials into clinical practice
- Accelerating the transfer of knowledge from cancer care delivery research studies into healthcare systems and organizations

The current CCOP agenda for clinical trials is expected to be continued under NCORP as its predominant activity. Specifically, the NCORP agenda is expected to include the following aspects:

- Cancer prevention research aimed at identifying and evaluating interventions to reduce cancer risk and incidence
- Cancer control research aimed at reducing the incidence and co-morbidity of cancer and its treatment and enhancing the quality of life of those affected by cancer
- Cancer screening/post-treatment surveillance research aimed at evaluating early diagnosis and recurrence of cancer
- Secondary endpoints of health-related quality of life or patient reported outcomes on NCTN treatment trials

New areas of special emphasis will include studies addressing mechanisms of cancer symptoms and treatment-related toxicities, molecularly-targeted agents to understand toxicities, post-treatment surveillance, underdiagnosis and overdiagnosis, and management of precancerous lesions. Post-treatment surveillance studies will evaluate the use of optimal screening/post-treatment surveillance modalities or tumor markers designed to detect recurrences of cancers following curative intent. Methods of diagnosis for cancers will be collected within NCORP trials to facilitate the research required to evaluate overdiagnosis and underdiagnosis of cancers (e.g., screening interval breast cancers).

NCORP will also build an infrastructure and research agenda for cancer care delivery research that includes the following:

- Developing the necessary data and informatics infrastructure and site training for the conduct of studies
- Analyzing new or existing data to better understand current patterns of cancer care in the community setting
- Observational studies of the effect of alternative care models on patient outcomes (e.g., patterns of care or service utilization; health behavioral improvement programs; organizational structures such as integrated

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healthcare systems versus free-standing hospitals; organizational policies such as reimbursement arrangements)

- Interventional studies of approaches (single and multi-level studies) to improve care delivery practices across the cancer care continuum (e.g., decision-making tools to support genomically-informed diagnostic testing or therapies), new approaches for team-based care, such as multi-modality therapy planning and delivery, patient navigation or other care processes to evaluate care transitions and the incorporation of patient reported information into clinical decision-making)

The NCORP cancer disparities research agenda will integrate into clinical trials and cancer care delivery research studies, as appropriate, the following:

- Studies to enhance participation of racial/ethnic and other underserved populations underrepresented in research (e.g., reminder systems)
- Studies that address determinants of disparities (e.g. social factors, health care system factors, co-morbidities, genomics) that disproportionately affect outcomes for racial/ethnic and underserved populations
- NCORP's operating approach will share the principles underlying the transformation of the national cancer clinical trials enterprise and the creation of the NCTN. Essential features include:
- A coordinated and collaborative process involving broad representation from the oncology community, including: academic and community clinical investigators, translational science investigators, statisticians, medical informaticists, patient advocates, health services, behavioral, and disparities researchers, and healthcare administrators, for generating concepts for clinical trials and care delivery research studies
- Evaluation of concepts for clinical trials and cancer care delivery research for scientific merit by NCI-managed steering committees composed of leading experts from the extramural community in cancer prevention, control, screening/post-treatment surveillance, care delivery and disparities, community oncologists and patient advocates, consistent with national priorities for cancer prevention, control and screening/post-treatment surveillance trials and cancer care delivery research
- Efficient and timely activation, conduct, and completion of studies, through the effective integration of scientific expertise with operational management capabilities
- Incorporation of innovative science into clinical trials and cancer care delivery research studies through collaboration with institutions and investigators conducting basic or early phase clinical trial research relevant to cancer prevention, control and screening/post-treatment surveillance as well as those conducting exploratory research on new care delivery approaches and methodologies.

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D. Organization of Key Components of NCORP

The NCORP Network is comprised of 3 components: (1) NCORP Research Bases; (2) NCORP Community Sites; and (3) NCORP Minority/Underserved Community Sites.

Each of these key components is described briefly below.

1. NCORP Research Bases

An NCORP Research Base is defined as a research hub for the NCORP. Research Bases must be located at leading institutions with comprehensive expertise in cancer clinical trials, such as institutions that are cancer foundations, healthcare research organizations (including sites of Clinical Trials Cooperative Groups or NCTN Group Operations Centers), NCI-designated Cancer Centers, or integrated healthcare systems. These institutions must have an established organizational structure for the design and conduct of multi-center cancer prevention, control and screening/post-treatment surveillance clinical trials and cancer care delivery research. Each NCORP Research Base will have an integrated organizational structure encompassing scientific leadership, statistics, clinical trial and study operations, data management, and administration.

The Research Base will provide scientific leadership for developing and implementing multi-disciplinary, multi-institutional cancer prevention, control and/or screening/post-treatment surveillance trials, HRQOL studies embedded within treatment and imaging trials, correlative biomarker or imaging studies embedded within cancer prevention, control, screening/post-treatment surveillance and cancer care delivery research studies. The Research Base will be responsible for study operations including timely protocol development and management, compliance with Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP) regulatory and patient protection requirements, audits, training, quality assurance, and site support. It will also be responsible for providing the statistical expertise required to ensure effective scientific design and conduct of trials/studies as well as leadership in innovation in statistical methodology.

NCORP Research Bases are expected to collaborate with each other and with NCI to achieve the overall goal of the Program. Member institutions/sites of Research Bases will be able to enroll patients on all NCORP studies, irrespective of the specific Research Base that is leading the study. NCORP Research Bases will also provide trial operations, data management, and statistical support for approved, multi-center cancer prevention and control and cancer care delivery studies originating outside of the specific Research Base's Network.

With respect to cancer care delivery research, the Research Base will participate in the Cancer Care Delivery Research Coordinating Committee to coordinate the strategic development and prioritization of research topics and network-wide common data collection, reporting, auditing and training standards. The committee also shall establish requirements for engaging the broader health services, behavioral and

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outcomes research communities with NCORP and determine the scope and breadth of patterns of care and program characteristics data and organizational policies that will be requested from sites to support the development of study concepts.

Unlike the NCTN Network Groups, NCORP Research Bases will not have separate grants for their Operations and Group Statistics and Data Management Centers. NCORP will no longer provide funding for pre-clinical or early stage clinical studies performed by “prevention members” although NCI will continue to provide support for ongoing legacy studies developed by those members. However, Research Bases may continue to request funding for pilot studies.

2. NCORP Community Sites

An NCORP Community Site is defined as a consortium of community hospitals and/or oncology practices or a community-based integrated healthcare system that accrues participants to: 1) cancer prevention, control and screening/post-treatment surveillance clinical trials designed and conducted by NCORP Research Bases; 2) NCTN-sponsored cancer treatment and imaging trials, as well as quality of life studies embedded within them; and 3) cancer care delivery research studies (where “participants” can be defined as patients, clinicians, and/or healthcare organizations). The sites will need to demonstrate the ability to meet or exceed the required annual 80 new patient/participant accruals evenly distributed over cancer prevention, control and screening/post-treatment surveillance trials and treatment and imaging trials, respectively.

The component site(s) within an NCORP Community Site designated to perform cancer care delivery research (at least one site is required) will be expected to develop and enhance their data collection and study implementation capabilities related to cancer care delivery research, provide organizational data (e.g., financial, service utilization, processes of care, policies) in support of studies, and provide site mentoring (as appropriate) in cancer care delivery research. These component sites also will be expected to participate in network-wide CCDR site data assessment initiatives, integrate these findings to improve their ability to participate in cancer care delivery research and actively seek participation in cancer care delivery research study concepts that are appropriate to their organization and data collection capabilities.

3. NCORP Minority/Underserved Community Sites

An NCORP Minority/Underserved Community Site is defined as a consortium of community hospitals and/or oncology practices, a public hospital, or academic medical center that has a patient population comprising at least 30% racial/ethnic minorities or rural residents. Minority/Underserved Community Sites will accrue participants to: 1) cancer prevention, control, and screening/post-treatment surveillance clinical trials designed and conducted by NCORP Research Bases; 2) NCTN-sponsored cancer treatment and imaging trials, as well as quality of life studies embedded within them; and 3) cancer care delivery research studies (where “participants” can be defined as patients, clinicians, and/or healthcare organizations). Established

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Minority/Underserved Sites will be expected to meet or exceed the required annual 80 new patient/participant accruals evenly distributed over cancer prevention, control and screening/post-treatment surveillance trials and treatment and imaging trials, respectively. Under special circumstances, a NCORP Minority/Underserved Community Site (excluding eligible NCI-Designated Cancer Centers) may be allowed to reach the required annual 80 new participant/patient accruals by the end of the project period. Additionally, Minority/Underserved Community Sites will mentor NCORP Community Sites in disparities-focused research and will identify relevant research questions emanating from their communities.

The component site(s) within an NCORP Minority/Underserved Community Site designated to perform cancer care delivery research (at least one site is required) will be expected to develop and enhance their data collection and study implementation capabilities related to cancer care delivery research, provide organizational data (e.g., financial, service utilization, processes of care, policies) in support of cancer care delivery research studies, and provide site mentoring (as appropriate) in cancer care delivery research. These component sites will also be expected to participate in network-wide cancer care delivery research site data assessment initiatives, integrate these findings to improve their ability to participate in cancer care delivery research studies and actively seek participation in cancer care delivery research study concepts that are appropriate to their organization and data collection capabilities.

E. Interactions with Other NCI-Supported Programs

In addition to the 3 key components that are described above and will be directly funded by NCORP, other NCI grant and contract supported Programs and their awardees as well as NCI Advisory Committees will have important supporting roles in carrying out the research objectives of NCORP. Thus, NCORP awardees will be expected to interact as appropriate with such entities/programs as NCTN, NCI Clinical Trials Tumor Banks, the NCI Cancer Trials Support Unit, the pediatric and adult NCI Central Institutional Review Boards, research programs of the Center to Reduce Cancer Health Disparities, and NCI Advisory and Scientific Committees including the NCI Scientific Steering Committees.

1. National Clinical Trials Network (NCTN)

NCORP Community Sites and Minority/Underserved Community Sites are expected to accrue to NCTN treatment trials. NCORP Research Bases are not funded to develop or conduct treatment and imaging trials.

2. NCI Clinical Trials Tumor Banks

The advent of powerful molecular technologies and the emergence of targeted therapeutics have opened the door to developing more effective and, in some cases, individualized treatment of patients with cancer aimed at specific cancer-related pathways. Understanding risk and mechanisms of disease related symptoms and treatment related toxicities may be enhanced by specimen collection in conjunction with NCORP studies. Development of effective interventions, based on

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comprehensive analysis of critical pathways of cancer initiation and progression, requires access to biological specimens from patients treated in prospective studies. High-quality biological specimen banks containing uniformly collected specimens from such studies along with validated clinical and outcome data are essential for development and delivery of new diagnostic and predictive tools to guide the use of targeted therapies. In particular, key components of NCORP conducting phase 3 clinical trials are uniquely positioned to provide high-quality biologic specimens associated with detailed information regarding method of diagnosis (screen-detected versus symptomatic), treatment histories, recurrence data, and careful follow-up from patients over long periods of time.

NCORP Research Bases are encouraged to consider conducting ancillary/correlative studies. Such studies may be amenable to funding through the Biomarker, Imaging, and Quality of Life Studies Funding Program (BIQSFP) or alternative funding (e.g., AHRQ, PCORI) mechanisms but the studies must be reviewed and approved by DCP before protocol initiation.

The infrastructure needed to ensure the collection of high-quality, well annotated human specimens from NCORP treatment studies is funded and administered by DCTD through the NCTN Cooperative Agreement awards. Review of research project requests for use of biospecimens banked from NCORP trials is also administered by DCTD through the NCTN Program. The infrastructure to support banking of the biospecimens collected from NCORP studies is funded and administered through a separate U24 Cooperative Agreement award.

For information on the U24 Cooperative Agreement award mechanism administered by the Cancer Diagnosis Program (CDP) in DCTD, see RFA-CA-09-504 entitled "Support for Human Specimen Banking in NCI-Supported Cancer Clinical Trials" at <http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-09-504.html>.

These biological specimen banks function under the rules developed for this U24 Cooperative Agreement and the funding provided by the U24 Cooperative Agreement award is intended to support the activities necessary to operate a well-developed bank.

A Research Base may request funding under NCORP to cover costs for staff/personnel to coordinate activities with the associated tumor banks for its clinical trials/studies. NCORP Research Base award will also allow for the costs of specimen collection. NCORP studies originating from NCTN Network Groups that collect tumor specimens can be stored at banks falling under Human Specimen Banking U24 awards. Cancer Center NCORP Research Bases will have the option to either store tumor specimens at their own institutions or to contract with centers with Human Specimen Banking U24 awards.

3. NCI Cancer Trials Support Unit (CTSU)

The Cancer Trials Support Unit (CTSU) is a service of the National Cancer Institute's (NCI) Cancer Therapy Evaluation Program (CTEP) developed to provide administrative support for phase 3 and select

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phase 2 clinical trials conducted by the NCTN Program, select NCORP cancer prevention, control and screening/post-treatment surveillance clinical trials, and other NCI-supported clinical trial programs. It is strongly encouraged that the CTSU be utilized for all NCORP clinical trials. It is anticipated that use of the CTSU will become a future requirement for all of NCORP cancer prevention, control and screening/post-treatment surveillance trials by the end of the initial five year funding cycle.

The CTSU provides the following support for NCORP:

- facilitates access to trials conducted by NCORP;
- provides 24/7 centralized, web-based, patient enrollment via the Open Patient Enrollment Network (OPEN), supported by Research Base membership rosters and institutional review board (IRB) approvals provided via the Regulatory Support Services (RSS); and
- provides support for the Common Data Management System (CDMS), including remote data entry, and helps to harmonize procedures and policies related to operational aspects of trial conduct across NCORP.

More information regarding the CTSU, including other services and new initiatives, is available at:

<http://www.ctsu.org>.

4. NCI Central Institutional Review Boards (CIRBs)

All U.S. institutions/sites participating in NCORP studies are required to use the NCI Central Institutional Review Board (CIRB) for any NCORP study under the NCI CIRB's purview. The NCI CIRB provides a centralized approach to human subject protection through a process that streamlines local IRB review of adult and pediatric national multi-center cancer treatment trials. The Initiative consists of two central IRBs, one for adult trials and one for pediatric trials.

At the present time, the pediatric CIRB reviews all NCORP phase 2 and phase 3 trials and pilot studies with pediatric populations. Under the current CIRB model, the CIRB conducts full Board review of a new study, the local IRB chair or an IRB subcommittee at participating institutions reviews the CIRB materials for local context and if approved, the CIRB becomes the IRB of record for the life of that study. All adult NCTN treatment trials are mandated to use the CIRB or an IRB of equal capacity. Adult NCORP trials do not currently utilize the CIRB process. See <http://www.ncicirb.org> for information on the requirements for a signatory institution under the NCI CIRBs.

The benefits to research participants include study review by individuals who represent a broad range of oncology expertise including patient advocates, oncology physicians, nurses and other health professionals as well as ethicists. The benefits to local IRBs include the ability to carry out local review without convening the entire Board. Continuing reviews, amendments and non-local adverse events (AEs) are handled

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by the CIRB as well. The benefits to investigators include time saved since they can download an already completed IRB application for each study as well as eliminating the need to submit amendments, continuing reviews and non-local AEs to their IRB. In addition, subjects are enrolled in trials faster since the full local IRB does not need to meet.

5. Research Programs of the Center to Reduce Cancer Health Disparities (CHCRD)

CRCHD initiates, conducts, integrates, and engages in collaborative research studies with NCI Divisions, Offices and Centers, and other NIH Institutes and Centers to promote research and training in cancer health disparities research and to identify new and innovative scientific opportunities to improve cancer outcomes in communities experiencing an excess cancer burden. CRCHD's cancer disparities research programs include the Partnerships to Advance Cancer Health Equity (PACHE), Community Networks Program Centers (CNPC), and a portfolio of cancer disparities researchers and trainees in basic, behavioral, clinical, translational, and population-based science.

- PACHE enables partnerships between institutions serving racial/ethnic and/or underserved communities with cancer health disparities and NCI-Designated Cancer Centers (CCs). PACHE is designed to increase the participation of the institutions serving racial/ethnic and/or underserved communities with cancer health disparities in cancer research and research training; and increase the involvement and effectiveness of NCI-designated Cancer Centers (CCs) in developing effective research, education, and outreach programs to encourage diversity among competitive researchers and reduce cancer health disparities.
- CNP Centers focus on eliminating disparities in specific target communities—identified by their shared interests, needs, and values—using a Community Based Participatory Research (CBPR) approach. By working in partnership with these communities, the CNP Centers seeks to increase the knowledge, access, and use of prevention measures (like smoking cessation and mammography) and treatment options (like advanced chemotherapy) in order to reduce cancer disparities in target populations; conduct CBPR interventions examining the best ways to promote prevention and treatment at multiple levels; and train qualified health disparities researchers in the CBPR approach and promote their career development.

In addition, the National Outreach Network (NON) is a network of Community Health Educators (CHEs) embedded within NCI's cancer disparities outreach and research programs. Working through CHEs, NON seeks to enhance NCI's ability to develop and disseminate culturally appropriate, evidence-based cancer information that is tailored to the specific needs and expectations of diverse racial, ethnic, and underserved communities.

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The benefits to NCORP include access to diverse racial, ethnic and underserved communities with established clinical and community-based partnerships. Collaborations and partnerships with these research and outreach programs will enhance the integration of a disparities focus within NCORP, increase opportunities to identify, design, and develop research questions and interventions aimed at reducing cancer disparities, and educate the oncology community about disparities in access to care, quality of care and cancer care outcomes, as well as effective strategies to reduce barriers to participation in clinical trials and improve patient involvement in their cancer care.

More information regarding the CRCHD, including its diverse research and outreach programs, is available at: <http://crchd.cancer.gov>

6. NCI Advisory & Scientific Committees

The NCI Advisory and Scientific Steering Committees associated with clinical trials and translational research activities funded by the NCI are described briefly below. Information on these Advisory Committees is available at: <http://ccct.cancer.gov/committees/overview> and information on the NCI Scientific Committees is available at: <http://transformingtrials.cancer.gov/steering/overview>. The NCI Coordinating Center for Clinical Trials (CCCT) is the administrative organization overseeing the activities of these Committees. General information on CCCT is available at: <http://ccct.cancer.gov/about/overview>.

NCI Clinical Trials and Translational Research Advisory Committee (CTAC)

The NCI Clinical Trials and Translational Research Advisory Committee (CTAC) is an external oversight committee, governed by the provisions of the Federal Advisory Committee Act, that advises the NCI Director on the NCI-supported national clinical and translational research enterprises, including both intramural and extramural research. Committee members include leading authorities in clinical trials and translational research. The CCCT Director serves as the Executive Secretary for CTAC and the CCCT staff facilitates operations. General information on CTAC is available at: <http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm>.

The CTAC Strategic Planning Subcommittee for the NCTN and NCORP evaluates the clinical trial portfolio across these programs and provides recommendations to CTAC regarding the evaluation decisions of the NCI Scientific Steering Committees (e.g., NCI disease-specific Steering Committees, Clinical Imaging Steering Committee) and reviews the overall trial portfolio for gaps and balance among the different disease areas and modalities.

NCI Scientific Steering Committees (SSCs)

The NCI Scientific Steering Committees strive to enhance the NCI's entire clinical trials enterprise through implementation of prioritization and scientific quality initiatives under the purview of

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the NCI Clinical Trials and Translational Research Advisory Committee (CTAC). General information on the NCI Steering Committees is available at:

<http://transformingtrials.cancer.gov/steering/overview>.

The NCI SSCs are composed of leading cancer experts and advocates from outside the Institute and NCI senior investigators who meet regularly to:

- increase the transparency and openness of the trial design and evaluate concepts for scientific merit;
- enhance patient advocate and community oncologist involvement in clinical trial design and prioritization; and
- convene Clinical Trials Planning Meetings to identify critical questions, unmet needs, and prioritize key strategies.

The NCI SSCs most relevant to the work of NCORP are the Symptom Management and Quality of Life Scientific Steering Committee and the Clinical Imaging Scientific Steering Committee. The Symptom Management and Quality of Life Steering Committee evaluates symptom management intervention clinical trial concepts conducted through NCORP for scientific merit and provides expertise to review quality of life studies embedded within treatment trials. The Clinical Imaging Steering Committee evaluates large primary advanced imaging studies for scientific merit and provides expertise to review imaging components embedded within treatment trials. All NCORP concepts related to cancer screening/post-treatment surveillance, prevention, and surveillance are evaluated by the Division of Cancer Prevention (DCP) Concept Review Committee (PRC), with ad hoc extramural scientific reviewers, as needed. In the future, NCI may develop a standing Screening, Prevention, and Surveillance Scientific Steering Committee, or utilize such a Committee on an ad hoc basis, to evaluate relevant clinical trial concepts for scientific merit.

The NCI plans to develop a standing Cancer Care Delivery Research Scientific Steering Committee. This Committee would evaluate all NCORP concepts related to cancer care delivery research for scientific merit. Until the existence of said committee, NCORP concepts related to cancer care delivery research will be evaluated by the Division of Cancer Control and Population Sciences (DCCPS) Concept Review Committee (CRC), with the assistance of ad hoc extramural scientific reviewers and review by DCP leadership.

NCI Clinical and Translational Research Operations Committee (CTROC)

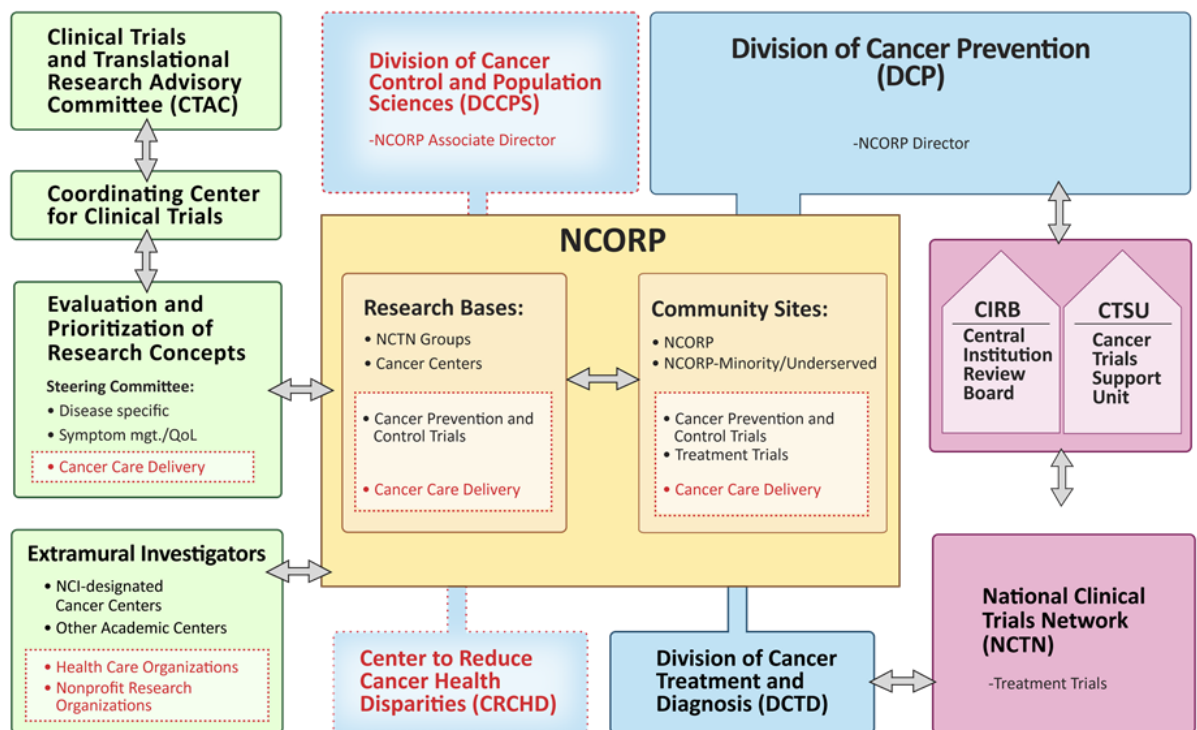
The Clinical and Translational Research Operations Committee (CTROC), an internal NCI advisory committee composed of representatives from NCI Divisions, Offices, and Centers involved

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in NCI-supported clinical trials and translational research, provides strategic oversight for NCI clinical trials and translational research programs and infrastructures, including informatics. The Committee reviews clinical trials and translational research programs proposed by Divisions, Centers, and Offices to coordinate efforts Institute-wide. CTROC also oversees and approves applications under the Biomarker, Imaging, and Quality of Life Studies Funding Program (BIQSFP) to support integral and integrated biomarker, imaging, and quality of life studies as well as Cost-Effectiveness Analysis (CEA) proposals which are associated with Research Base clinical trial concepts approved for conduct under NCORP that are eligible for BQSFP funding. Information on the BQSFP is available at: <http://bigsfp.cancer.gov/>.

F. Organizational Structure for the NCI Community Oncology Research Program (NCORP)



II. Types of Research in NCORP

The primary goal of NCORP research is to develop and conduct cancer prevention, control, and screening/post-treatment surveillance trials and health-related quality of life (HRQOL) and cancer care delivery studies with prominent involvement of community oncologists, other specialists, and the populations they serve. An equally important focus of NCORP is an emphasis on trials/studies in minority and underserved populations.

A. Cancer Prevention Research

Cancer prevention research is defined as clinical evaluations of the effectiveness of interventions for the purpose of reducing the risk for developing cancer (including but not limited to chemopreventive agents, surgical interventions, and lifestyle modifications). Randomized controlled trials of interventions are of highest priority for NCORP. In select circumstances, observational studies may also be considered by the Program.

B. Cancer Screening Research

Cancer screening research is defined as clinical evaluations of methods for the early (pre-symptomatic) detection of cancer and precancerous lesions. Randomized controlled trials of interventions are of highest priority for NCORP. In select circumstances, observational and longitudinal studies may also be considered by the Program.

C. Post-Treatment Surveillance Research

Post-treatment surveillance research is defined as clinical evaluations of methods for earlier detection of cancer recurrence. Randomized controlled trials of interventions are of highest priority for NCORP. In select circumstances, observational studies may also be considered by the Program.

D. Cancer Control Research

Cancer control research is defined as clinical evaluations of interventions to improve patients' quality of life and/or to treat symptoms arising from cancer or toxicities arising from cancer therapy as well as ways to improve continuing, palliative, and end-of-life care. Randomized controlled trials of interventions are of highest priority for NCORP. In select circumstances, pilot, observational and natural history studies may also be considered by the Program to inform the development of future randomized controlled trials. In addition, studies to understand mechanisms of symptoms and toxicities are encouraged.

E. Cancer Care Delivery Research

Cancer care delivery research is defined as the multidisciplinary field of scientific investigation that studies how complex, multi-level forces, including social factors, financing systems, organizational structures and processes, health technologies, provider and individual behaviors affect cancer outcomes, access to cancer care, the quality and cost of cancer care and ultimately the health and well-being of cancer patients and survivors.

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Types of Research in NCORP: *Biospecimen Collection*

Its focus includes individuals, families, organizations, institutions, providers, communities, populations and their interactions.

The envisioned studies may be observational or interventional in design. Observational studies may address the effect of alternative care models on patient outcomes (e.g., patterns of care or service utilization; organizational policies; health behavioral improvement programs; organizational structures such as integrated healthcare systems versus free-standing hospitals). Interventional studies may address implementation of new technologies (e.g., decision-making tools to support genomically-informed diagnostic testing or therapies), new approaches for team-based care, such as multi-modality therapy planning and delivery, patient navigation and other approaches to evaluate care transitions, and/or incorporation of new types of information (e.g., patient reported information) into clinical decision-making, etc.

F. Cancer Treatment Trials

NCORP Research Bases are not funded to design or implement cancer treatment trials. However, NCORP Community sites and NCORP Minority/Underserved Community sites are expected to accrue participants to cancer treatment trials designed and conducted under the NCTN Program.

G. Health-Related Quality of Life Sub-Studies

NCORP Research Bases are funded to develop hypothesis-driven HRQOL studies embedded in treatment or imaging trials as secondary endpoints to inform the primary endpoints in the trials. These secondary endpoints are usually measured by patient-reported outcomes that provide critical data for patient/clinician treatment decisions and acceptance of new therapies.

H. Correlative Science Sub-Studies

The patient, provider and organizational information accumulated in the course of NCORP clinical trials/studies provide the Research Bases with unique opportunities to address scientific questions about molecular genetics, epidemiology, pathology, and other topics that pertain to cancer prevention and control (e.g., risk assessment, premalignant lesions, toxicities of therapy) and cancer care delivery research (e.g., patient report outcomes, clinical decision-making). Such investigations can add considerable strength to a Research Base's total scientific program and are encouraged. While integral or integrated studies associated with a phase 3 or large, randomized phase 2 trial may be eligible for financial support through the Biomarker, Imaging, and Quality of Life Studies Funding Program (BIQSFP) at: <http://bigsfp.cancer.gov/>, a variety of other funding mechanisms – including investigator-initiated grants (R01s, P01s), Cooperative Agreements and industry, foundation or other government funding for discrete projects (U01s, U19s) may also be appropriate for funding correlative science sub- studies, especially those ineligible for BIFSFP funding.

I. Biospecimen Collection

Although NCORP supports the collection of biospecimens in conjunction with clinical studies and cancer care delivery studies conducted by the Research Bases, direct funding for correlative science studies using those

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: *Cancer Disparities* Research

specimens outside of BIQSFP and/or specific NCI/DCP approved administrative supplements for specific studies is not provided under or in association with NCORP. Access to biospecimens collected in conjunction with an NCORP study for research studies will be guided by the appropriate review process (see Part 1: Section IV.C.3. of these Guidelines) regardless of the funding source used for the collection or storage of the biospecimens.

J. Cancer Disparities Research

The NCORP cancer disparities research agenda will integrate the following types of studies into clinical trials and cancer care delivery research studies, as appropriate:

- Studies to enhance participation of racial/ethnic and other underserved populations underrepresented in research (e.g., reminder systems)
- Studies that address determinants of disparities (e.g. social factors, health care system factors, co-morbidities, genomics) that disproportionately affect outcomes for racial/ethnic and underserved populations
- Studies that address new therapies and delivery approaches to improve access and patient outcomes

III. NCORP General Management, Operating and Funding Principles

A. General Management

Direct programmatic oversight of NCORP is provided by the NCI Division of Cancer Prevention (DCP) and its programs. The Chief of the Community Oncology Prevention Trials Research Group (COPTRG), DCP, NCI is the Director of NCORP. The Chief of the Outcomes Research Branch, Applied Research Program, Division of Cancer Control and Population Sciences (DCCPS), is the Associate Director, as DCCPS provides guidance and oversight related to cancer care delivery research performed within NCORP. The Director and Associate Director work with Program Directors for the key components of NCORP and NCI/DCP or DCCPS Program Management staff and the DCP Senior Program Specialist to oversee NCORP. For cancer care delivery research-related tasks, NCI/DCCPS Research Associates will provide project management support as needed.

NCI/DCP and DCCPS staff involved with NCORP also work closely with NCI staff from the Division of Cancer Treatment and Diagnosis (DCTD), especially program staff within the Cancer Therapy and Evaluation Program (CTEP) for the National Clinical Trial Network (NCTN) Program, to manage NCORP as NCORP Community Sites and Minority-Underserved Community Sites participate directly in the clinical trials of the NCTN and NCTN Network Groups can serve as NCORP Research Bases. NCI/DCP and DCCPS staff involved with NCORP work closely with NCI staff from the Center to Reduce Cancer Health Disparities (CRCHD) to facilitate the integration of cancer disparities research questions into clinical trials and cancer care delivery studies and to participate in the review of concepts. General information on DCP, DCCPS, DCTD, CRCHD is available from the NCI public website at the URLs listed below:

- NCI Division of Cancer Prevention (DCP): <http://prevention.cancer.gov/>
- NCI Division of Cancer Control and Population Sciences (DCCPS): <http://cancercontrol.cancer.gov/>
- NCI Division of Cancer Treatment and Diagnosis (DCTD): <http://dctd.cancer.gov/>
- NCI/DCTD Cancer Therapy Evaluation Program (CTEP): <http://ctep.cancer.gov/>
- NCI Center to Reduce Cancer Health Disparities (CRCHD): <http://crchd.cancer.gov/>

B. NCORP Management

1. NCORP Leadership Management Committee

The NCORP Leadership Management Committee is composed of the key members of NCI/DCP and NCI/DCCPS involved in the direct

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III. NCORP General Management, Operating and Funding Principles: ***NCORP Management***

programmatic oversight of NCORP, representatives of NCI/DCTD and the senior leaders of the Research Bases involved in the direct management of clinical trials and cancer care delivery research. This management committee makes recommendations regarding the policies, procedures, and conduct of NCORP to the NCI as described in Part 1 – Section IV of these Guidelines. The goal is for the NCI/DCP, NCI/DCCPS and extramural NCORP senior leadership to work collaboratively in managing the Program.

2. Cancer Care Delivery Research Coordinating Committee

NCORP will have a designated Committee to coordinate efforts in cancer care delivery research. The Committee will be convened jointly by the NCI and NCORP Research Base awardees. Initially, the committee will consist of the following members:

- Two leadership representatives from each Research Base (PDs/PIs or other senior investigators), of whom at least one has expertise in cancer care delivery research; and
- Representatives from the NCI.

These initial members of the Committee will decide on its final composition, structure, procedures, etc. Community Sites and Minority/Underserved Community Sites will be represented on an ad hoc basis. Additional representatives of Research Bases and NCI as well as external experts may also be involved in the activities of the Committee, e.g. as ad hoc members.

The specific functions of the Committee are expected to include:

- Developing an agenda and research priorities for NCORP cancer care delivery research;
- Promoting and coordinating cross-NCORP scientific collaboration;
- Standardizing various aspects of NCOR cancer care delivery research, including (but not limited to):
 - Data definitions, collection tools and procedures especially for abstraction of financial, service utilization, quality monitoring and registry data;
 - Tools and procedures for linking EMR with financial and service utilization data; common NCORP repositories of data from NCORP community sites (e.g., cancer registry data, processes of care data, and data on organizational characteristics and policies);
 - Timeline requirements for study development, activation and standard data;
 - Standard audit requirements and procedures; and
 - Common training and simulation protocols for community sites.

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III. NCORP General Management, Operating and Funding Principles: **NCORP Operating** Principles

C. NCORP Operating Principles

As described in the background section of these Guidelines, the purpose of the new NCORP is to provide standing support for a consolidated and integrated national Network that conducts cancer prevention, control and screening/post-treatment surveillance and care delivery research on an ongoing basis. In NCORP, Research Bases will collaborate with each other and with NCI to achieve the research objectives of NCORP based on operating principles that stress harmonization of procedures used by the individual Research Bases and their member institutions/sites. This includes the use of standard tools and services for clinical trial and cancer care delivery research conduct (e.g., common data elements) to ensure that NCORP trials/studies are developed and conducted as efficiently as possible and with collaboration and coordination among the Research Bases and other NCI-supported program and investigators.

1. Access to NCORP Trials & Crediting for Patients Accrual to Trials

Research Bases' member institutions/sites will be able to enroll patients/participants to NCORP cancer prevention, control and screening/post-treatment surveillance clinical trials led by their affiliated NCORP Research Bases and those available on the CTSU irrespective of affiliations. In addition, member institutions/sites will be able to enroll patients on all adult phase 3 treatment trials (and selected phase 2 treatment trials), irrespective of the specific Network Group which is leading the study. Community Sites and Minority/Underserved Community Sites will be able to credit treatment enrollments to any Network Group to which they belong. Enrollments to prevention, control and screening/post-treatment surveillance trials through CTSU may be credited by the Community Site to any of its affiliated NCORP Research Bases, based on their crediting rules. It is anticipated that affiliates of institutional members of a particular Research Base will follow the crediting decision of the main member for a particular trial; however, that is at the discretion of the Research Bases through their membership rules.

Note: International sites (i.e., non-U.S. sites) that are members of NCORP Research Bases may not be able to participate in all NCORP studies because of special regulatory issues specific to the country of the international member. The Research Base must specify any potential restrictions related to enrollment from international members prior to trial activation. For trials being conducted under an NCI/DCP IND, this information must be reviewed and approved by NCI prior to trial activation.

2. Submission of Data and Biospecimens

All data, as well as any biospecimens collected, must be sent by the institutions/sites participating in a trial to the Network Group that is leading the NCTN trial, or to the NCORP Research Base that is leading the NCORP trial or study unless an exception is approved by NCI to accommodate the needs of a specific trial/study.

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3. Use of the NCI Central Institutional Review Board

All U.S. institutions/sites participating in NCORP studies are required to use the NCI Central Institutional Review Board (CIRB) for any NCORP study under the NCI CIRB's purview. The NCI CIRB provides a centralized approach to human subject protection through a process that streamlines local IRB review of adult and pediatric national multi-center cancer treatment trials. The Initiative consists of two central IRBs, one for adult trials and one for pediatric trials. Adult NCORP trials do not currently utilize the CIRB process. See <http://www.ncicirb.org> for information on the requirements for a signatory institution under the NCI CIRBs.

4. Study Proposals Originating From Outside the Research Bases

All cancer prevention, control and screening/post-treatment surveillance trials and cancer care delivery research studies to be conducted within NCORP must be through a Research Base. If a study has been peer-reviewed by a federal agency, it will be submitted to DCP PIO as a protocol via a Research Base and reviewed for feasibility within NCORP and budgetary overlap only. Studies outside of federal agency organizations will be reviewed as a concept. In special circumstances, administrative supplements may be provided to Research Bases to help support study conduct and integral/integrated translational science based on a direct solicitation for a study from NCI/DCP, particularly for studies addressing health disparities and/or underserved populations.

5. Collaborations Among Research Bases and with Other Organizations on Clinical Trials/Studies

Research Bases are encouraged to collaborate with other Research Bases and with other NCI-funded programs and investigators (e.g., NCI-designated Cancer Centers, Early Phase Cancer Prevention Consortium, Early Detection Research Network, Center to Reduce Cancer Health Disparities, NCI Cancer Research Network, R01 and P01 investigators). These collaborations may include advancing research ideas from pilot studies to phase 3 trials, joint-participation and sharing of evidence-based practices in cancer care delivery and disparities research studies and other research endeavors. Research addressing specific toxicities (such as cardiotoxicity and neuropathy) is an area where collaboration is especially encouraged. These efforts could include but are not limited to setting standard definitions, identifying common data elements, developing mutual outcome measures and collecting data across the network in a consistent manner. Research Bases are encouraged to engage investigators with expertise in these areas and to collaborate with each other and with other NIH institutes and other federal agencies in research to address gaps in understanding the biology of toxicities and symptoms which prevent the development of interventions as well as the use of comparative effectiveness and patient-reported outcomes in assessing toxicities and symptoms, and designing trials/studies to improve clinical practice

6. Compliance

Researchers have an obligation to take appropriate steps to protect both the integrity of science and the human subjects who participate in

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research studies. Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human subjects. Research Bases as well as all other key components of NCORP should strive to comply with this standard to the greatest degree possible since it provides public assurance that the rights, safety, and well-being of study participants are protected, and that study data are credible. Information on GCP standards in FDA-regulated Clinical Trials is provided at: <http://www.fda.gov/oc/gcp/default.htm>.

The integrity of study data is a function of the entire process of data collection and analysis. Research Bases as well as the other key components of NCORP need detailed Quality Control and Quality Assurance plans and systems to assure protocol adherence in the administration of protocol-prescribed interventions and observational studies in the uniform collection of data. Vigilance to detect honest errors, whether systematic or random, as well as data falsification, is especially important since independent replication of most studies is not feasible.

D. NCORP Network Funding Principles

1. Grant Funding for Key Components of NCORP

The allowable costs under the Cooperative Agreements for each of the key components of NCORP are described under the budget section of the application process for new applications in Part 2 of these Guidelines. In general, the funds can support costs associated with personnel (e.g., operational staff, scientific and administrative committees leaders, principal investigators for specific studies), travel, appropriate equipment, and other operational costs related to the conduct of clinical trials/studies; however, costs for patient recruitment, patient care and laboratory tests are generally not allowed under the grant funding for NCORP, however, support may be considered on a case by case basis. Support for patient recruitment may be requested for underserved or underrepresented populations in clinical research.

2. Funding for Research Bases

2.1 Total Budget

The budget of a Research Base is divided into two parts: (1) a clinical trials budget which includes costs for cancer prevention, control and screening/post-treatment surveillance clinical trials as well as HRQOL studies embedded within treatment and imaging trials and (2) a cancer care delivery research budget. During the start-up and initial phase of NCORP the expected relative balance in level of effort between clinical trials and cancer care delivery research will be approximately 90% and 10%, respectively, for a given Research Base.

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2.2 Clinical Trials Budget

The clinical trials budget has two elements: (1) infrastructure costs for developing, conducting and analyzing NCORP clinical trials and HRQOL studies and (2) costs for reimbursing member institutions/sites that are not funded as a NCORP Community Site or Minority/Underserved Community Site (hereinafter referred to as "institutional members") for data collection and management and biospecimen collection associated with subject enrollment to NCORP clinical trials and HRQOL studies ("per case management" costs). The total cost infrastructure budget is dependent on the projected accrual to clinical trials and HRQOL studies led by the Research Base and the total cost per case management budget is dependent on projected accrual by the Research Base's institutional members to the clinical trials and HRQOL studies that it leads as well as to those led by other Research Bases that the institutional member is expected to credit to the applicant Research Base. Guidelines include examples for estimating these costs in Part 4 – Appendices – Section IV. The applicant is not required to follow these instructions, as these are provided as examples, only.

2.3 Cancer Care Delivery Research Budget

The cancer care delivery research budget has two elements: (1) costs for the scientific and statistical leadership, data systems/informatics and management infrastructure necessary to develop, conduct and analyze cancer care delivery research studies ("infrastructure costs") and (2) costs to cover study operations, statistical analysis, data management, quality control, study monitoring and auditing for studies led by the Research Base ("study-specific costs"). No per case management costs for institutional members should be budgeted as only NCORP Community Sites and Minority/Underserved Community Sites will be funded to participate in cancer care delivery research studies.

Because cancer care delivery research was not a focus of activity under the previous CCOP Research Base awards, the expectation is that the balance of infrastructure costs versus study specific costs will evolve over the course of the initial award period for each Research Base. In the initial award year, the proposed budget for a Research Base is expected to be 100% infrastructure costs as likely no cancer care delivery research studies will have yet been developed and approved and it will take time to develop a scientific, statistical, data systems, informatics and management infrastructure to support this area of research. Over the remaining award years, the percentage devoted to study specific costs is expected to increase, reaching a steady state of approximately 75% of the total Research Base budget for cancer care delivery research. The remaining 25% will continue to provide infrastructure support in terms of scientific and statistical leadership, data systems, informatics and management. However,

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funding from other sources can be used to augment the cancer care delivery research efforts.

3. Funding of Sites for Clinical Trial Data Collection/Management & Biospecimen Collection

NCI funding for institutions participating in all NCORP trials/studies to cover the costs related to data collection/management and biospecimen collection associated with enrolled patients ("per case management funding") is provided in two ways:

- Grant funding from NCI to NCORP Community Sites and Minority/Underserved Community Sites
- Grant funding from NCI to NCORP Research Bases which then contract with their institutional members via purchase service or subcontract agreements on a "per-case" basis.

In keeping with the need for collaboration across NCORP, funding for clinical trial data collection and management and biospecimen collection is provided in a consistent manner for institutions/sites that enroll patients on NCORP studies. For NCORP Community Sites and Minority/Underserved Community Sites, each clinical trial approved by NCI will be assigned a credit value by NCI/DCP. Credits will be based on the complexity of the intervention, the amount of data management required, and the duration of follow-up. However, in general, cancer treatment, prevention, control and screening/post-treatment surveillance trials will receive one credit per accrual ("intervention" credits) ; health-related quality of life and advanced imaging studies will receive 0.5 credits per accrual ("imaging and quality of life credits"); molecular screening and biospecimen collection will receive 0.1 credits per accrual ("supplementary credits"). The credit is claimed one time by Community or Minority/Underserved Community Site grantees against the grant year in which the participant was enrolled on the protocol.

NCORP Community Sites and Minority/Underserved Community Sites that received more than 200 credits annually during the past three years as "intervention" and "imaging and quality of life" credits may be eligible to use a "high performance" per case management funding dollar amount of \$4000 per credit. Past experience indicates high accruing sites may need additional resources to compensate for the patients that are in follow-up over multiple future years. Community Sites that consistently received less than 200 credits during the past three years in these categories may only qualify for a "basic" per case management funding amount of \$2500 per credit. All applicants must provide justification for the amount requested based on actual costs to be incurred. The credits used to determine budgets/funding for NCORP Community Sites and Minority/Underserved Community Sites will be based on accrual to all NCTN and NCORP trials regardless of which NCORP Research Base is credited with the accrual by the enrolling site.

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“Supplementary” credits will not count toward achievement of the 200 credit threshold.

For per case payments to institutional members, a standard “unit” value of \$500 has been established. Cancer prevention, control and screening/post-treatment surveillance trials will receive 4.5 units per accrual; HRQOL studies will receive two units per accrual; and molecular screening and biospecimen collection will receive one unit per accrual.

Any separate, non-NCI/DCP funding (i.e., funding not provided under the Cooperative Agreements of NCORP) or any NCORP funding provided as a separate administrative supplement that is dispensed by a Research Base to cover costs associated with patient enrollment on NCORP trials/studies that it leads (“**Special Per Case Management Funding**”) must be provided to all qualified institutions/sites that participate in the relevant NCORP trial/study regardless of which Research Base the enrolling institution belongs to and/or credits with the patient accrual. This principle is considered an essential feature of NCORP and the Terms and Conditions of Award as it is fundamental to ensure fairness for work performed across the NCORP Network.

3.1 Per Case Management Funding Categories for Clinical Trials

The various funding categories for NCI/DCP supported studies are described below.

- **Prevention:** Funding to cover data management and follow-up for subjects enrolled in prevention trials (chemoprevention, secondary prevention). Research Bases can request support for recruitment of non-cancer patients on a study-by-study basis.
- **Cancer control:** Funding to cover data management for patients enrolled in interventional or observational cancer control research studies aimed at reducing the incidence and co-morbidity of cancer and its treatment and enhancing the quality of life of those affected by cancer.
- **Screening/Post-treatment surveillance:** Funding to cover data management for patients enrolled in screening or post/treatment surveillance studies (e.g., imaging, biomarkers).
- **Treatment:** Funding to cover data management and follow-up for patients enrolled in a treatment trial who undergo the study intervention and/or randomization.
- **Health-Related Quality of Life:** Funding to cover data management for patients enrolled in HRQOL studies embedded in treatment or imaging trials as secondary endpoints including those using patient-reported outcomes.

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- **Advanced Imaging:** Funding to cover data management for subjects enrolled in advanced imaging studies
- **Molecular Screening:** Funding to cover data management costs for patients enrolled on a trial that require specific screening with informed consent as part of the trial (e.g., investigational molecular test of their tumor) and who do not subsequently undergo the study treatment/intervention and/or randomization because of the screening results. Per case management funding is provided for molecular screening **or** for one of the other categories listed below but never for both.
- **Biospecimen Collection Per Case Management Funding:** Funding to cover biospecimen collection and any associated biospecimen management costs for subjects enrolled on studies which require biospecimen collection and for subjects who agree to participate in optional biospecimen collections associated with trials. This category of funding would not be expected to be given in association with molecular screening per case funding except in unusual circumstances.

4. Funding of Sites for Cancer Care Delivery Research

NCORP Community and Minority/Underserved Community Sites must identify at least one component site that will participate in cancer care delivery research studies and provide a budget for each component site so designated that includes the following elements:

- Costs for overall scientific and management leadership and coordination for research program
- Costs for study coordinator and data system staff to conduct studies

Because cancer care delivery research was not a focus of activity under the previous CCOP awards, the expectation is that the majority of the Community Site budget in the initial award year will be for evaluating and enhancing the informatics and data collection/reporting capabilities with regard to cancer care delivery research at the designated component site(s) and in training their research and data systems staff in this area of research. In subsequent award years, the funding is expected to move primarily toward supporting participation in specific studies. Because the funding for cancer care delivery research is limited in the initial award period, funding from other sources can be used to augment the cancer care delivery research efforts at the community sites although such funding will flow through the Research Bases.

At a minimum, Community Site funding for cancer care delivery research activities is expected to support approximately 5% time for a lead investigator who provides scientific oversight of the cancer care delivery research program and approximately one staff FTE to support data management and study coordination for at least one component site designated for participation in cancer care delivery research.

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Community Sites with (1) one or more component sites with demonstrated experience and capacity in cancer care delivery research; (2) one or more component sites with additional data collection capabilities (e.g., linking registry, medical records and administrative data); and/or (3) more than one component site with the interest and capacity to conduct cancer care delivery research will be candidates for increased levels of funding. The total cost budget request from Community Sites with additional component sites and/or enhanced capacity may qualify for higher levels of funding. The budget justification should clearly delineate the proposed use of funds requested.

5. Program Income for Key Components of NCORP

Under the Cooperative Agreement grants awarded for all key components of NCORP, awardees are allowed to accept funds from non-governmental sources to support NCORP research that is not supported in part or in full by the NCI (e.g., additional funding supplementing the NCI/DCP basic intervention funding, support for correlative science studies associated with trials/studies conducted under NCORP, nonprofit foundation support for cancer care delivery research). Awardees also are allowed to receive and use funds from other governmental funding mechanisms (e.g., R01s) related to the specific research study. NCORP studies using alternative funding must still be reviewed and approved by NCI. These funds are considered "Program Income" and must be reported under the Terms and Conditions of Award for the key components of NCORP as outlined in Part 1 - Section IV.A.2. of these Guidelines unless they are exempted under the NIH grant policy for program income available at: http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch8.htm# Program Income. These funds are considered a valuable resource to help further the research objectives of the entire Program. Nevertheless, the Cooperative Agreements for NCORP always define the operational principles under which the awardees must function to ensure the independence of the research conducted regardless of whether program income is or is not available for specific clinical trials/studies conducted by NCORP.

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IV. Terms & Conditions of Award for Cooperative Agreements for NCORP Key Components:
***General Terms and Conditions* of Award for All Key Components of NCORP**

IV. Terms & Conditions of Award for Cooperative Agreements for NCORP Key Components

A. General Terms and Conditions of Award for All Key Components of NCORP

The administrative and funding instrument used for all of the key components of the NCI Community Oncology Research Program (NCORP) is a Cooperative Agreement (U10 as outlined in the table in **Part 2 – Section 1.A. of these Guidelines**).

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below.

1. General Programmatic Responsibilities

The awardees' programmatic responsibilities for the conduct of the research supported under the Cooperative Agreement for each of the key components of NCORP are described in the documents listed below and any subsequent modifications to these documents:

- NCI Community Oncology Research Program (NCORP) Guidelines (i.e., "these Guidelines") <http://prevention.cancer.gov/ncorp>
- NCI National Clinical Trials Network (NCTN) Program Guidelines http://ctep.cancer.gov/investigatorResources/default.htm#guidelines_policies
- NCI/CTEP Investigators Handbook (Manual for Participants in Clinical Trials of Investigational Agents Sponsored by the Division of Cancer Treatment and Diagnosis, NCI) <http://ctep.cancer.gov/handbook/index.html>
- Guidelines for Monitoring of Clinical Trials for Cooperative (i.e., Network) Groups, CCOP Research Bases, and the Cancer Trials

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Support Unit (CTSU)

http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_copp_ccop_ctsu.htm

Specific portions of these documents, as enumerated in the Funding Opportunity Announcement for each of the key components of NCORP (as well as in specific sections of the NCORP Guidelines), are incorporated by reference as program-specific Terms and Conditions of Award.

2. Program Director(s)/Principal Investigator(s) Primary Responsibility & Program Income Reporting

The PD(s)/PI(s) will have the primary responsibility for:

- Development of an overall research strategy for the NCORP components
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, NIH, and NCI policies and within the limits of any accepted binding NCI/NIH collaborative agreements with biotechnology and pharmaceutical partners and as governed by NCI-approved Data Sharing Plans and NCI-approved review for use of biospecimens collected in association with NCORP trials/studies.
- Awardees are allowed to accept funds from non-governmental sources to support NCORP research that is not supported in part or in full by the NCI. Awardees also are allowed to receive and use funds from other governmental funding mechanisms (e.g., R01s) related to the specific research study. Any study associated with NCORP must still be reviewed and approved by NCI. These alternative funds are considered "Program Income" (i.e., additional funding supplementing the NCI/DCP base funding, or support for correlative science studies associated with trials/studies conducted under NCORP) and must be reported under the Terms and Conditions of Award for NCORP unless they are associated with an exempted category under the NIH grant policy for program income, available at:

http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch8.htm#_Program_Income.

All key components of NCORP must report these funds to the NCI on an annual basis (in the non-competitive Type 5 application – the annual progress report) and must indicate the trial/study (or functional component of the study) that the funds are being used to support. The Terms and Conditions of Award for all the Cooperative Agreements under NCORP define the operational principles under which the awardees must function to ensure the independence of the research conducted regardless of whether program income is or is not available for any of the awards.

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- Programmatic responsibilities for the individual key components of NCORP are described in detail under "Specific Cooperative Agreement Terms & Conditions of Award for the Key Components of NCORP" in Part 1 – Section IV.B. of these Guidelines.

3. NCI Staff Programmatic Responsibility

NCI staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below.

The NCORP Director and Chief, Community Oncology Prevention Trials Research Group (COPTRG), DCP, is the NIH/NCI Program Official responsible for the routine scientific and programmatic stewardship of all the awards for NCORP and will be named in the award notice. The NCORP Associate Director and Chief, Outcomes Research Branch (ORB), Applied Research Program, DCCPS, will also be named in the award notice for some components of NCORP as he/she has major responsibilities in assisting the NCORP Director for the scientific and programmatic stewardship of the awards as specifically related to cancer care delivery research.

Each key component of NCORP will have a staff physician, nurse, and/or other professional staff member from DCP/COPTRG or DCCPS/ORB assigned to them who will have substantial programmatic involvement above and beyond normal stewardship role in awards, acts as liaison for scientific and administrative matters. NCORP will have programmatic evaluation and approval from DCTD staff for treatment clinical trials. These DCP/COPTRG or DCCPS/ORB Program Directors serve as the primary contact for scientific and administrative inquiries. On occasion, the NCORP Director or Associate Director may also serve as Program Directors

The NCI Program Director (s) will attend peer review meetings in accordance with NIH guidelines.

A DCP/COPTRG or ORB Senior Program Specialist may also be delegated by the NCORP Director to perform liaison activities with the key components of NCORP on budgetary and administrative matters.

The main NCI responsibilities are related to research efforts of NCORP Research Bases and NCORP Community and Minority/Underserved Sites and include but are not limited to the following activities:

For NCORP Research Bases:

- Serving as scientific liaisons to awardees of key components of NCORP and participation in scientific meetings of the key components; Informing NCORP Program investigators of scientific opportunities resulting from NCI-supported research programs;
- Review of the annual type 5 budget request;
- Oversight of data and safety monitoring plans and boards for NCORP clinical trials;

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- Oversight of data management and monitoring programs for NCORP research studies as well as onsite auditing programs and quality assurance programs for NCORP, including oversight of core services for radiotherapy and imaging supporting NCTN clinical trials;
- Facilitating coordination of the research activities and collaborations between NCORP and other NCI-sponsored programs and investigators;
- Facilitating the evaluation of research concepts and protocol development as well as review of correlative science study requests for use of biospecimens collected in association with NCORP studies;
- Advising awardees concerning mechanisms established for quality control of therapeutic and diagnostic modalities; and
- Monitoring the progress and performance of NCORP
- Responsibilities as a drug sponsor for investigational agent or device development for NCI-sponsored or co-sponsored IND and/or IDE clinical trials; and
- Ensuring compliance with FDA requirements for investigational agents and ensuring compliance with OHRP and other federal requirements and regulations for research involving human research subjects;

For NCORP Community and Minority/Underserved Community Sites:

- Working with NCORP Community Sites to collaboratively manage major issues associated with their participation in trials/studies across NCORP and the NCTN Network;
- Oversight of quality assurance and auditing activities relating to compliance with Federal regulations, NCI policy and CTMB audit guidelines via their membership in the NCORP and NCTN Network;
- Review of accrual and overall performance of NCORP Community Sites;
- Review of compliance with applicable DHHS, FDA, OHRP, NIH, and NCI regulations for research involving human research subjects;
- Review and advise awardees on mechanisms for quality control/monitoring, including on-site auditing program;
- Monitoring the progress and performance of this key component of NCORP, and
- Review and approval of organizational changes

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Programmatic responsibilities for NIH Staff are completely described under "NCI/DCP/DCCPS Responsibilities" in **Part 1 – Section IV.C.** of these Guidelines.

The NCI will have access to all data collected and/or generated under this Cooperative Agreement and may periodically review the data. The NCI may also review all records related to awardees' performance under the award for appropriate collection, review, and distribution of biospecimens collected in association with NCORP studies.

In case of inability to meet the scientific aims of the Cooperative Agreement or noncompliance with the Terms and Conditions of Award, the NCI reserves the right to reduce award budget, withhold support, suspend, or terminate an award.

4. Joint Responsibility

Areas of Joint Responsibility include:

- General aspects of collaboration on study development and conduct: compliance with federal regulations for cancer care delivery and clinical trial research (including ensuring that the clinical information obtained would be acceptable to the FDA for inclusion in a potential licensing application, if applicable); participation in Data and Safety Monitoring Boards; development of collaborative and international trials; use of standard NCORP common tools and services;
- Collective management of NCORP including participation in the NCORP Leadership Management and cancer care delivery research Coordinating Committees;
- Review of recommendations from the NCI Clinical Trials and Translational Research Advisory Committee (CTAC) on strategic directions for NCORP.

Joint programmatic responsibilities for the awardees of the key components of NCORP and the NIH staff are completely described under "Collaborative Responsibilities (Awardees of NCORP Key Components and NCI/DCP/DCCPS)" in **Part 1 – Section IV.D.** of these Guidelines.

5. Dispute Resolution

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to Dispute Resolution, except for areas of dispute that are already addressed by the appeal process within the Terms and Conditions of Award for decisions regarding approval of study proposals and the types of studies supported by NCORP as described in **Part 1 – Section IV.E.** of these Guidelines.

For other scientific and programmatic matters that are not covered by the appeals process, a Dispute Resolution Panel composed of three members will be convened. It will have three members: a designee of the Network Group representatives on the NCORP Leadership

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Management Committee chosen by them without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two. In the case of individual disagreement, the first member may be chosen by the individual awardee. The appeals process and this special dispute resolution procedure do not alter the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

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B. Specific Terms and Conditions of Award for the Key Components of NCORP

1. Specific Awardee Rights & Responsibilities - NCORP Research Bases

An NCORP Research Base is defined as a program research hub. Research Bases must be located at leading institutions with comprehensive expertise in cancer clinical trials, such as institutions that are cancer foundations, healthcare research organizations (Including sites of Clinical Trials Cooperative Groups or NCTN Group Operations Center), NCI-designated Cancer Centers, or integrated healthcare systems. These institutions must have an established organizational structure for the design and conduct of multi-center cancer prevention, control and screening/post-treatment surveillance clinical trials and cancer care delivery research. The Research Base provides scientific and statistical leadership for developing, implementing, and analyzing multi-institutional cancer prevention, control, and screening/post-treatment surveillance clinical trials, quality-of-life studies embedded within treatment and imaging clinical trials and cancer care delivery research studies. The Research Base is responsible for study operations and data management, including timely protocol development, compliance with Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP) regulatory and participant protection requirements, audits, training, quality assurance, and site support.

The Research Base is responsible for developing and implementing its own Constitution and By-laws. The Constitution and By-laws should define the organizational structure, composition, and specific responsibilities of each Research Base committee (scientific and administrative) as well as study teams and membership for institutions/sites. Integration with the administrative structure of the National Clinical Trials Network (NCTN) is anticipated.

General responsibilities of the PDs/PIs of the NCORP Research Bases include the following areas:

- Overseeing the development and conduct of the clinical trials and cancer care delivery research.
- Ensuring scientific rigor of all the conducted studies and other research activities;
- Overseeing the content and direction of the NCORP Research Base's cancer prevention and control research program and cancer care delivery research;
- Prioritizing the plans and clinical trials in the context of the NCORP Research Base's overall scientific objectives;
- Participating in the activities of the NCORP Cancer Care Delivery Research Coordinating Committee and adhering to all scientific and policy decisions of this committee to the extent consistent with grant regulations.

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- Assuring compliance of the participating investigators and institutions with all Human Subjects Requirements and other applicable regulations.
- Ensuring that appropriate Quality Assurance/Quality Control mechanisms are in place for complete and accurate data collection.
- Submitting annual Progress Report PHS 2590 to the NCI Program Official;
- Attending periodic NCI strategy meetings and participating, as appropriate, in NCI Scientific Steering Committees; and
- Overseeing all other activities and specific responsibilities of Research Base defined below.

1.1 Clinical Trial and Cancer Care Delivery Development Program

1.1.1 Overall Responsibilities for Cancer Prevention and Control

Clinical Trials

It is the responsibility of the NCORP Research Base to develop and articulate an overall research strategy related to cancer prevention, control, screening/post-treatment surveillance and health-related quality of life. This includes clinical evaluations of the effectiveness of interventions for the purpose of reducing the risk for developing cancer (including, but not limited to, chemo-preventive agents, surgical interventions, and lifestyle modifications); development of risk assessment models; methods for the early detection of cancer and management of precancerous lesions (i.e., screening) or for the earlier detection of cancer recurrence (i.e., post-treatment surveillance); interventions to improve patients' quality of life and/or to treat symptoms arising from cancer or toxicities arising from cancer therapy; and ways to improve continuing, palliative, or end-of-life care. Such studies are aimed at reducing cancer incidence, morbidity, mortality, and cancer disparities through the identification, testing, and evaluation of effective and appropriate strategies and interventions.

It is the responsibility of the Research Base awardee, in accordance with its constitution, bylaws, policies, and procedures, to develop the details of the research design, including definition of objectives and approaches, planning, implementation, analysis, publication of results, interpretations, and conclusions of the studies. The Research Base awardee is responsible for statistical leadership for NCORP clinical trials, including developing the statistical research design and analysis plan, statistical analysis, appropriate interim monitoring plans, interpretations, and conclusions in regard to study data.

The Research Base is also responsible for all aspects of data management. It must have Standard Operating Procedures

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(SOPs) covering all aspects of data management, study monitoring, and data analysis for NCORP studies. The SOPs should include plans for training NCORP investigators and Clinical Research Associates (CRAs) at member participating sites and Study Chairs and Study Teams about their responsibilities for data management and study monitoring. The Research Base must also have the appropriate facilities and equipment, especially with respect to information technology, to provide for complete data management for all aspects of NCORP studies.

1.1.2 Overall Responsibilities for Cancer Care Delivery Research Studies

It is the responsibility of the NCORP Research Base to develop and articulate an overall research strategy related to cancer care delivery. Cancer care delivery research is the multidisciplinary field of scientific investigation that studies how complex, multi-level forces, including social factors, financing systems, organizational structures and processes, health technologies, provider and personal behaviors affect access to cancer care, the quality and cost of cancer care, and ultimately the health and well-being of cancer patients and survivors. Its focus includes individuals, families, organizations, institutions, providers, communities, populations and their interactions. Cancer care delivery research studies may be observational or interventional in design.

Observational studies related to cancer care delivery research include but are not limited to patterns of care or service utilization, alternative organizational structures (e.g. integrated healthcare systems versus free-standing hospitals) or alternative models for implementing multidisciplinary care planning.

Interventional studies include but are not limited to implementation of new technologies (e.g., decision-making tools to support genomically-informed diagnostic testing or therapies), new approaches for team-based care, such as multi-modality therapy planning and delivery, patient navigation and other approaches to evaluate care transitions, and/or incorporation of new types of information (e.g., patient reported information) into clinical decision-making.

It is the responsibility of the Research Base awardee, in accordance with its constitution, bylaws, policies, and procedures, to develop the details of the research design, including definition of objectives and approaches, planning, implementation, analysis, publication of results, interpretations, and conclusions of the studies. The Research Base awardee is responsible for statistical leadership for NCORP cancer care delivery studies, including developing the statistical research design and analysis plan, statistical

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analysis, appropriate interim monitoring plans, interpretations, and conclusions in regard to study data.

The Research Base is also responsible for all aspects of data management. It must have Standard Operating Procedures (SOPs) covering all aspects of data management, study monitoring, and data analysis for NCORP studies. The Research Base must have the appropriate facilities and equipment, especially with respect to information technology, to provide for complete data management for all aspects of NCORP cancer care delivery research studies. This includes responsibility for maintaining an NCORP-wide repository of data obtained for NCORP Community and Minority/Underserved Community component sites, (e.g. cancer registry data, processes of care data and data on organizational characteristics and policies). The Research Base must also have SOPs for training NCORP cancer care delivery research investigators and Clinical Research Associates (CRAs) at member participating sites and Study Chairs and Study Teams about their responsibilities for data management and study monitoring for NCORP cancer care delivery research studies including standardized training and simulation exercises for medical record abstraction and extraction of data from financial and administrative data systems.

1.1.3 Overall Research Strategy for Disparities Research Studies

NCI defines "cancer health disparities" as "differences in the incidence, prevalence, mortality, and burden of cancer and related adverse health conditions that exist among specific population groups." Disparities research questions must be an identifiable component of a Research Base's research strategy. Cancer disparities research questions embedded in clinical trials might include randomized recruitment approach among a specific underserved population or pharmacogenomics comparisons between two racial/ethnic populations. For cancer care delivery research, this includes 1) emphasis on research questions involving gaps in access to and quality of care, 2) specialized data collection requirements to support such studies (e.g., SES data collection). , and 3) innovative delivery approaches to improve the access to and quality of care.

1.1.4 Scientific Research and Administrative Committees

The Research Base is responsible for establishing scientific research committees and administrative committees for both clinical trials and cancer care delivery research studies and developing a process for the selection of leadership for these committees. The Research Base should ensure that committees involve appropriate representation from relevant stakeholders, including a range of clinical experts, behavioral

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and health services researchers, and patient advocates. The Research Base is responsible for establishing clear operating principles and procedures for committees and facilitating their operations by arranging meetings and establishing and maintaining electronic communication tools.

Scientific Research Committees: Scientific research committees are defined as committees that function primarily to develop and oversee the conduct of clinical trials and HRQOL and cancer care delivery research studies within a defined strategy (e.g., cancer prevention and control; observational research)

The primary responsibilities of the scientific research committees are to develop study concepts and oversee protocol development and study conduct for approved studies. Through these processes, feasibility of accrual and other types of participation will be considered,, including minority/underserved accrual and participation will be addressed. Further, the Committees will help develop the Research Base's overall research strategy including research questions addressing cancer health disparities.

Correlative science studies, especially integral and integrated studies, are increasingly central to the interpretation of clinical trials data, particularly for studies of molecularly targeted agents. Scientific research committees play a key role in the development and conduct of correlative science studies associated with Research Base protocols. Funding for integrated and integral correlative science studies is not provided by the NCORP award (except in exceptional circumstances via an administrative supplement by NCI/DCP for a specific study) but may be applied for via the Biomarker, Imaging, and Quality of Life Studies Funding Program (BIQSFP) for phase 3 and randomized phase 2 trials. Information on the BIQSFP is available at:

<http://bigsfp.cancer.gov/> (see also Part 1, Section I.E.2 of these Guidelines). Other sources of funding may be sought for correlative science studies that are not eligible for BIQSFP funding (e.g., other NCI and NIH grant funding, industry funding); however, the study must still be reviewed by NCI.

Study Monitoring by Scientific Committees & Study Teams: The primary responsibility for study monitoring resides with the Study Chair, Study Statistician, and other members of the study team that help develop and oversee conduct of a specific study. The relevant scientific research committee is responsible for assuring that the study team is satisfactorily meeting its responsibilities for study monitoring.

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Administrative Committees: Administrative committees for clinical trials are defined as committees that provide essential core service functions to help effect other aspects of the Research Base's research strategy (e.g., Membership, Auditing, Conflict of Interest). Administrative committees responsible for cancer care delivery research also provide essential core services and could include cancer registrars, hospital administration, and financial managers.

1.1.5 Young Investigator Mentoring/Training

The Research Base is responsible for having a mentorship program to involve young investigators in cancer prevention, control, screening, and cancer care delivery research and to help train them eventually to take on leadership responsibilities for trials/studies, and/or committees.

1.1.6 Communications Support

The NCORP Research Base is responsible for organizing and disseminating information about the Research Base's scientific activities and major changes in administrative policies and procedures to its members through annual or biannual meetings that review the Research Base's progress, establish priorities, and plan future activities. Additional meetings among Research Base members and meetings with NCI staff may be held as needed. Relevant Research Base responsibilities for meetings include: (a) arranging for appropriate meeting space and accommodations for attendees; (b) developing and distributing meeting agendas; and (c) preparing summaries as appropriate after each meeting for Research Base members and NCI staff.

The Research Base is responsible for establishing routine communication between itself, member sites participating in its studies, and, where applicable, the Cancer Trials Support Unit (CTSUS), to facilitate protocol development and study conduct and monitoring. Relevant communication methods include website postings, e-mail, teleconferences, and video-conferences.

1.1.7 Publications

The NCORP Research Base is responsible for ensuring timely preparation and submission of all Research Base publications for peer review. **Research Bases must adhere strictly to the publication policy described in these Terms and Conditions of Award.**

Acknowledgement of NCI Support and Scope of Publication Policy: Publication or oral presentation of work done via the Research Base's Cooperative Agreement requires appropriate acknowledgment of NCI support. The definition of publications for this Cooperative Agreement includes NCORP Research Base abstracts, press releases, print-media articles/manuscripts,

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electronic media articles/presentations, letters, etc., related to findings and results from NCI-sponsored studies. All NCORP Research Base publications must reference the NCI protocol title in the manuscript or abstract title whenever relevant to the publication.

Publication Timelines: Timely publication of NCORP Research Base findings is central to the mission of the Research Base and is a primary means by which the Research Base's accomplishments can be evaluated. Timely presentation of a study's findings and results is especially important when a DMSB recommends the public release of this information. Timely presentation of cancer care delivery research study findings and results is especially important when related to public policy and clinical practice standards.

It is expected that preliminary results of major phase 3 trials and large definitive care cancer delivery studies will be presented at a scientific meeting within 6 to 8 months of completion of the study analysis (if not sooner based on the relevance of the results). It is a requirement under the Terms of Awards that a full manuscript on the study results be prepared and submitted for publication in the peer-reviewed literature (not as an abstract) within 1 year of the availability of the primary study results based on the completion date of the study recorded in the U.S. National Library of Medicine database, clinicaltrials.gov. Exceptions to this policy must be approved in writing by the NCORP Director. These timelines may be modified in the future by NCI institute-wide requirements that are in development.

It is also a requirement of these Terms of Award that the results of all NCORP studies be submitted as required by the Food and Drug Administration Amendments Act (FDAAA) Section 801 to comply with the rules defined for inclusion of clinical trial information in clinicaltrials.gov.

Pre-Publication Review:

- For cancer care delivery research publications associated with NCI-sponsored NCORP Research Base studies, the NCORP Associate Director must receive a copy of the manuscript or abstract 30 days in advance of publication. No review or comments will be provided unless specifically requested by the Research Base; this is simply a confidential notification. Review timing for publications other than abstracts or manuscripts should be discussed with appropriate NCI/DCCPS staff. No pre-publication review is required for NCORP clinical trial publications.
- All press releases issued by the NCI and/or the Research Base on primary study findings and results require review

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by NCI, NIH, and DHHS. Pre-review timing for press releases on study finding and results must be discussed with and approved by the NCORP Director and Associate Director for all cancer care delivery research studies. Research Bases are encouraged to send drafts of press releases on other topics to NCI for pre-review and/or pre-release notice.

- In addition to the requirements listed above, Research Bases should consider carefully whether any findings from clinical trials or cancer care delivery research studies that are pending reporting/publication may have major impact for public health or public policy. If there is the potential for major impact for public health or public policy, the Research Base must inform NCORP Director and Associate Director and work closely with NCI to ensure that the information is released to the public in as timely a manner as possible and in a manner to ensure appropriate communication about the results, including how they may affect other ongoing trials and the treatment of patients on those trials, public policy or current clinical practice.

Post-Publication Reporting & Submission to NIH Manuscript System:

- In their competitive Type 1 and non-competing Type 5 applications, Research Bases must report publication references for major clinical trial results and important associated studies to demonstrate the scientific accomplishments of their research strategy. Only references for the manuscripts for key findings should be reported. Copies of manuscripts cannot be submitted as part of the research plan or as appendix material.
- The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central *upon acceptance for publication*. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication. More information about this policy or the submission process is available on the NIH Public Access Policy website at: <http://publicaccess.nih.gov/>.

1.1.8 Data Rights

The NCI will have access to all data generated under this Cooperative Agreement and may periodically review the data. The awardee will retain custody and primary rights to the data consistent with current DHHS, Public Health Service (PHS), and NIH policies. Pharmaceutical and biotechnology companies will

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have access to all data generated under DCP Collaborative Agreements; however, the companies may contract directly with the Research Base for access to non-Clinical Data Update System (non-CDUS) data and reports. With respect to cancer care delivery research, external funding agencies and investigators that use the NCORP network to support scientific studies will have access to data from studies funded external to the network (e.g., PCORI and non-profit foundations).

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1.2 Membership Affiliation(s)

There are two types of NCORP Research Base Member Sites: Community and Minority/Underserved Community Sites and other institutional members. An NCORP Community Site is defined as a consortium of community oncologists from one or more interacting community institutions (e.g., hospitals, practices, integrated health systems) that accrue participants and/or provide secondary data to studies designed and conducted by NCORP Research Bases. The consortium may also include primary care and other providers. A Minority/Underserved Community Site is defined as a consortium of community hospitals, and/or oncology practices, a public hospital, or academic medical center with patient populations comprised of at least 30% racial/ethnic minorities or rural residents, that accrues participants and/or provides secondary data to studies designed and conducted by NCORP Research Bases. Other institutional members may be academic institutions and/or their associated affiliate members.

The Research Base is responsible for establishing, maintaining and monitoring all its members (i.e., Community and Minority/Underserved Community Sites and institutional members) that participate in NCORP trials/studies and credit the Research Base with patient accrual. The Research Base must have a “real time”, comprehensive, consolidated roster of all its members with their relevant CTEP institution codes, associated investigators and research staff. This roster must be incorporated into the CTSU Regulatory Support System (RSS) for auditing, financial management and crediting of enrollment purposes.

NCORP Research Bases must establish guidelines for Community and Minority/Underserved Community Site awardees and other institutional members to affiliate (i.e., become members). A Research Base must have established affiliation agreements with all member sites participating in that Research Base’s Network.

A Research Base is responsible for providing a portfolio of clinical trials and cancer care delivery research studies, a significant portion of which are feasible to implement in the community setting, are of scientific interest and address the clinical needs of the participating sites’ populations. Further, a Research Base must provide adequate resources (training, education, data management etc) for the participating sites to implement the studies. A Research Base will require a minimum number of clinical trial accruals by the participating sites that reflect their available studies and resources to conduct them.

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1.3 Operational Management

1.3.1 Governance, Organizational Structure, Policies & Procedures, and Membership

An NCORP Research Base is responsible for coordinating study proposals, protocol development, protocol submission, study conduct, performance reporting, quality assurance including quality control and study monitoring, protocol amendments/status changes, and adherence (where applicable) to requirements regarding investigational agent management as well as all federal regulations.

The Research Base is responsible for specifying the mix of funding available for a trial/study that it leads prior to trial/study activation (where applicable) as well as for providing information in a timely manner on appropriate modifications in funding on the trial/study during the course of accrual. Specific responsibilities of the Research Base include the following:

Governance: The Research Base is under the leadership of a “designated” Chair elected by the Research Base’s membership, who coordinates all the scientific and administrative decisions related to Research Base-funded activities and the Research Base’s institutional members. The Multiple Principal Investigator (PI) option is encouraged for the Research Base award given the team science approach of the research effort. Information on the Multiple PI Option is available at http://grants.nih.gov/grants/multi_pi/index.htm. If this option is used, the Research Base should designate a “Contact PI” among the multiple PIs. The designated Research Base Chair (or Contact Principal Investigator under the Multiple PI option) is also responsible for all grant-related activities and for communication about these activities with the appropriate NCI/DCP staff.

Organizational Structure, By-laws, and Standard Operating Procedures: The Research Base is responsible for development and maintenance of an organizational structure for the Research Base and its members/sites, including a Constitution and By-laws. The organizational structure of the Research Base should be established with clear and appropriate staff roles and reporting responsibilities, especially with respect to the role and reporting responsibilities of the Research Base Chair (who must also be listed as key personnel in the Research Base application and award). The Research Base is also responsible for the preparation and maintenance of Standard Operating Procedures (SOPs) that cover all aspects of its activities.

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The organizational structure should include the Scientific Research and Administrative Committees that the Research Base will need to support its research objectives as well any Executive Committee(s) that the Research Base elects to establish. There should be clearly defined term limits and succession/transition plans for the senior leadership of the Research Base and for the leadership of its committees. Terms for the key scientific leadership positions of a Research Base (e.g., designated Research Base Chair, Committee Chairs, etc.) should be limited to encourage participation by new investigators and to ensure a diversity of views over time. The process for filling elected positions for scientific leadership positions should be well described in the By-laws of the Research Base along with details of any exceptions to term limits.

1.3.2 Development of Concepts, Protocols, and Amendments for NCORP Cancer Prevention, Control, or Screening/Post-treatment Surveillance Clinical Trials or Cancer Care Delivery Research

These procedures apply to cancer prevention, control and screening/post-treatment surveillance clinical trials as well as cancer care delivery research studies except as specifically noted.

The Research Base shall designate Study Chair(s) for each proposed concept/protocol. The Research Base is responsible for establishing policies and procedures for the development and submission of NCORP Research Base study concepts and protocols through the NCI/DCP Protocol Information Office (PIO) for review and approval. The Research Base is also responsible for assembling appropriate study teams for protocol development and for overseeing conduct of approved studies.

Study concepts and protocols (as well as correlative science studies requesting use of biospecimens collected during the conduct of NCORP studies) should be developed, submitted, and implemented in accordance with DCP policies. Research Base SOPs should include timelines for the development of concepts and protocols from initial submission of the concept to NCI through study activation. The SOPs should also include mechanisms for monitoring the performance of the Research Base and Research Base committees and investigators in adhering to these timelines, as well as corrective action plans outlining steps to be taken when these timelines are not met. Data concerning a Research Base's performance in meeting these timelines for concept/protocol development should be

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provided in its Annual Progress Report. NCI may in the future establish expected timelines for development and activation of NCORP protocols.

1.3.2.1 Study Concept Development, Review, and Approval

The Research Base should have a detailed, specific study in mind before submitting a concept, and the concept should have been approved by all necessary components at the Research Base before submission to DCP. Although not a full protocol, the concept should provide sufficient information to establish the scientific rationale for the proposed study, describe the study methodology, and support the feasibility of conducting a successful study. Concepts do not need to include consent forms or case report forms, although they should include (as appendices) all of the questionnaires or measurement instruments to be used for the primary endpoint. Concepts may be no longer than 10 pages in length, excluding the title pages, references, and appendices.

1.3.2.1a Concept Content

Although DCP does not mandate the use of a set template for concepts, it does require specific information to be included in all study concepts. This information includes:

1) Title Page

- This is the primary source of identifying information for DCP PIO. Each concept must have a title page that contains:
- i. Date of document
 - ii. Local concept number (i.e., institution or group number)
 - iii. Title of study
 - iv. Clear identification as a clinical trial or cancer care delivery research study
 - v. Identified study personnel responsible for the study, including name, institution, address, phone and fax numbers, and email address
 - a) single study chair
 - b) co-chair(s)
 - c) related committee chairs
 - d) primary statistician
 - vi. Full name of Research Base submitting the study
 - vii. For agents requested from DCP, a listing of each agent by name and Cancer Chemotherapy National Service Center number (NSC Number)

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2) Background

This is the most important section of the concept, as it provides reviewers the rationale and scientific justification for conducting the study. It should contain:

- i. A detailed rationale for the study:
 - a) What is the current state of knowledge or clinical/care delivery practice?
 - b) Include preclinical, clinical and/or pilot data that support conducting the study
 - c) What will this study contribute to cancer prevention, control, or screening/post treatment surveillance or care delivery?
Although other contributions are important and should be included, this section should explain how information from the study would affect care of patients or the delivery of cancer care.
 - d) Why is the study design the best way to make this contribution?
 - e) Include information about the study population and intervention; the study populations could include patients, clinicians and/or organizations.
 - f) How will this research affect subsequent research?
 - g) How will the research inform patient care/improve patient outcomes?
 - h) Why were the endpoints chosen?
 - i) Justify choice of effect size and include power analysis
- ii. A literature review (a focused review of relevant literature with citations), which should cover:
 - a) Current knowledge
 - b) Other studies that have contributed information applicable to the study
 - c) Information on drugs, procedures and measurement instruments to be used
 - d) Other information justifying the research and its methodology:
- iii. Information related to feasibility:

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- a) State if NCORP Community Sites and Minority/Underserved Community Sites have been involved in developing or reviewing the concept
 - b) What is level of interest expressed by NCORP sites and how this information was elicited?
 - c) Note level of anticipated participation and accrual from NCORP sites and other members
 - d) Provide any additional data or information to support the anticipated accrual or participation rate
 - e) Specify procedures for recruitment and retention of participants (if applicable) including minority and underserved populations
 - f) If the study will involve costs in addition to data management, describe them and include a source of funding
 - g) Describe the time commitment of patients, research staff, physicians or other study participants
 - h) For cancer care delivery research studies, provide information on the anticipated availability of organizational, financial and other administrative data
- 3) Study objective(s)
- 4) Study design, including:
- i. Schema: This one-page diagram provides an overview of the study design. To be most useful, it should include:
 - a) Sample size
 - b) Study population
 - c) Stratification factors
 - d) Study design (e.g. randomization, case controlled, observational)
 - e) Specific intervention(s) (with dose, timing of data collection, etc.) if applicable
 - ii. Eligibility criteria and characteristics of study population
 - iii. Clear definitions of the primary and secondary endpoints

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- iv. Stratification factors and justification for using them
 - v. Detailed description of the intervention if applicable (including, for drugs, the provider; for complementary and alternative treatments, information on quality control and content; for behavioral or organizational interventions, the availability of resources in the community setting to provide the intervention, for procedural interventions, the willingness of the study populations to implement; for practitioner/organizational interventions, the availability of participants)
 - vi. Study Calendar or Study Parameters Table outlining the tests and observations to be performed and the timing of them
 - a) For pharmaceutical agents, including complimentary and alternative agents:
 - 1. Describe how agent will be provided, supported and assessed for quality control
 - 2. Document plan to submit protocol to FDA for IND review
 - b) For behavioral and organizational interventions:
 - 1. Describe availability of resources in community setting to provide intervention
 - 2. Document plan to train community sites to provide intervention
 - vii. Detailed methodology and explanation regarding how sub-studies (if applicable) will contribute useful information relevant to specified hypotheses.
5. Statistical analysis plan, including:
- i. Hypothesis
 - ii. Sample size calculation
 - iii. Estimated effect size
 - iv. Estimate of drop-outs/loss to follow-up
 - v. Plans for handling missing data

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- vi. Plan for analyzing the primary endpoint
- vii. Timing of data collection
- viii. Analysis plan for all sub-studies (if applicable)
- ix. Plans for addressing data limitations (if applicable)

1.3.2.1b Concept Submission

Investigators are encouraged to communicate with DCP Program Directors when developing concepts for clinical trials and HRQOL studies and with the DCCPS Program Directors when developing concepts for cancer care delivery studies. However, the final concept document and any relevant accompanying materials must be submitted to DCP's Protocol Information Office (PIO) electronically at NCI_DCP_PIO@mail.nih.gov. All new concepts must be accompanied by a fully completed Document Submission Worksheet (DSW). The latest version of these forms can be downloaded from <http://prevention.cancer.gov/clinicaltrials/management/io/instructions>. Subsequent submissions for the same concept also require the submission of the DSW.

In some circumstances investigators at Research Bases may wish to utilize the NCORP Network to support a study that has received approval through a peer review process and funding from a governmental or nongovernmental source other than NCORP grant (e.g., an R01). These studies need not be submitted as concepts but are still subject to DCP review and approval as full protocols (see Protocol Development, below).

1.3.2.1c Concept Review

NCI/DCP staff is responsible for facilitating the review process for proposed clinical trials and NCI/DCCPS staff is responsible for facilitating the review process for proposed cancer care delivery research studies. For concepts which fall within the purview of an established a Scientific Steering Committee (SSC) (e.g. the Symptom Management and Quality of Life

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Steering Committee or the to be established Cancer Care Delivery Steering Committee), the SSC conducts the review of the concept and determines the outcome of the review (i.e. approval, disapproval, or revise/resubmit). Prior to the review meeting of the SSC, the DCP Concept Review Committee for clinical trials and the DCCPS Concept Review Committee for cancer care delivery research reviews the concept and submits a letter of its findings with recommendations to the SSC to be included in its review. If NCI has not established a SSC with purview over a concept (e.g. a prevention or screening study), the DCP or DCCPS Concept Review Committee will be enhanced with extramural reviewers and will provide the sole review of the concept.

Prior to review by either a SSC or a Concept Review Committee, NCI program staff reviews each submitted concept to determine that the proposed research study is within the scope of NCORP research and that the concept document includes all required components and is not fully duplicative of existing studies. NCI program staff will return to Research Bases concepts that do not fulfill these criteria together with a letter that explains the reasons for not accepting the concept for review.

The review process is described in detail in Part 1, Section IV.C of these Guidelines (NCI/DCP and NCI/DCCPS staff Responsibilities).

1.3.2.2 Protocol Development, Review, and Approval

After receiving approval for a concept from the Division of Cancer Prevention, the Research Base should begin to formulate a protocol to conduct the proposed research. The protocol is a document that can be used by clinicians, research staff, Research Base, NCI, and others associated with the research to conduct the study. Because most elements of the concept are incorporated into the protocol, there is some redundancy. Because the utility of research and the scientific basis for conducting a study will change over time, concept approval expires on the due date included in the approval letter, which is usually within 3 months. If the Research Base intends to submit a protocol that will be received later than the due date, it

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should contact its program director for guidance. The Cancer Prevention and Control Protocol Review Committee assigns credit for each study at the time of protocol approval.

In some circumstances investigators may want to utilize the NCORP network for accrual to a study that has received federal funding (e.g. R01) outside of the NCORP U10 mechanism. These studies are submitted to the DCP PIO as protocols (not concepts) and are reviewed for feasibility of conduct within NCORP and the budget is reviewed for duplication. The protocol is not reviewed scientifically nor reviewed by a SSC.

1.3.2.2 Protocol Content

The protocol must include:

Document Submission Worksheet:

All new protocols must be accompanied by the Document Submission Worksheet (DSW). All relevant sections of the PSW must be completed. The latest version of these forms can be downloaded from <http://prevention.cancer.gov/clinicaltrials/management/io/instructions>. Subsequent submissions for the same concept also require the submission of the DSW.

Clinical trial protocols will not be approved until there is an IND exempt number or IND number and IND Holder listed on the title page of the protocol and provided in the DSW. The IND exempt letter from the FDA must be placed in the appendix of the protocol.

1.3.2.2a Cover Letter:

The cover letter includes point by point responses to issues (if any) raised in the concept approval letter and identifies places in the protocol that include changes relevant to these issues. The cover letter should also indicate any other significant changes made to concept and provide reasons.

If the protocol is for a study that will receive Government funding other than that in the NCORP grant and has received approval from a peer review panel, the cover letter should provide this

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information; a copy of the grant application, budget pages, and summary review statement should be included as attachments.

1.3.2.2b Title Page:

The title page of the protocol is the primary source of identifying information for the DCP Protocol Information Office (PIO), for the agent distribution system, for the IND file at the FDA, and for the listing of the protocol in the Physician Data Query (PDQ) system, as applicable. Each protocol submitted, therefore, must have a title page that contains the following items:

- i. Date of document
- ii. Local protocol number (i.e., institution or group number)
- iii. Title of study
- iv. A single protocol chair who will be responsible for the study, including name, institution, address, phone and fax numbers, and e-mail address
- v. List of the following study personnel including name, institution, address, phone and fax numbers and e-mail address
 1. Single study chair
 2. co-chair(s)
 3. related committee chairs
 4. primary statistician
 5. protocol coordinator
 6. data manager
 7. protocol contacts
- vi. Full name of Research Base submitting the study
- vii. List of each participating institution or Research Base (can be summarized as open to all Research Base members)
- viii. For DCP-supplied agents, a listing of each agent by name and NSC number (not applicable for cancer care delivery research)

1.3.2.2c Background:

The Background can largely be taken from the Background from the approved concept. It provides the reviewers the relevant arguments for conducting the proposed study. The Background section should be updated with recent relevant literature, information or discussion requested by

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the Concept Review Committee, or as appropriate based on changes to the protocol made after concept approval.

1.3.2.2d Detailed Schema:

1.3.2.2e Aims/Objectives:

1.3.2.2f Methodology:

- i. Characteristics of study population:
 - 1. Eligibility and ineligibility criteria
 - 2. Source of study participants
 - 3. Sampling, recruitment, and retention procedures (include estimates of minority recruitment and plans to increase minority recruitment, including participation of institutions intended to boost minority recruitment)
 - 4. Procedures for stratification (include stratification factors with definitions and justification for stratifying by these factors)
- ii. Plans for intervention:
 - 1. Detailed description of study design (e.g., randomized, quasi-experimental, case-controlled, observational)
 - 2. Detailed description of study intervention
 - 3. Schedule for administration of intervention (Agents – i.e. drugs and herbal/natural products – require dose, schedule, and duration; other interventions – e.g. behavioral/organizational - require details regarding implementation and any special training, facilities, and equipment). A training or procedure manual may be included as an appendix.
 - 4. Schedule for adjustments to planned intervention related to side effects (if applicable)
- iii. Plans for data collection:
 - 1. Number and timing of contacts with participants
 - 2. Data to be collected at each contact
 - 3. Rules for missed contacts (if applicable)
 - 4. Procedures to maximize response rates (if applicable)
 - 5. Procedures for administration of instruments and follow-up (if applicable)
- iv. Plan for missing data
- v. Definitions for primary and secondary endpoints; for observational studies, explanatory variables/composites.

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1.3.2.2g Drug Distribution:

- i. Plans for obtaining, storing, and distributing drugs and placebos. CAM agents must include information on testing of agent, product consistency etc
- ii. Special instructions for the intervention

1.3.2.2h Statistics:

- i. Define stratification factors with justification
- ii. Specify procedures to be used for randomizing subjects to treatment (or placebo) arms
- iii. Specify procedures to be used for assigning participants to intervention studies/trials. For observational studies describe statistical model and variables/composites used in the analysis.
- iv. Full plans for analyzing and interpreting results regarding the primary and secondary endpoints
- v. Sample size calculation and planned accrual rate
 - 1. Information on the composition of the proposed study population (accrual targets). For studies accruing patients, include information on sex/gender and racial/ethnic group in the format as provided on the DCP Document Submission Worksheet
 - 2. If the protocol is a NIH-defined Phase III trial (a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments), the investigator must address whether he/she expects to find clinically important sex/gender and/or race/ethnicity differences in the intervention effect. The protocol must include one of the following:
 - 1. Plans to conduct valid analyses to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies

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- strongly support these significant differences among subgroups, OR
2. Plans to include and analyze sex/gender and or racial/ethnic subgroups when prior studies strongly support NO significant differences in intervention effect between subgroups, OR
 3. Plans to conduct valid analyses of the intervention effect in sex/gender and/or race/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups

- vi. Analysis plan
- vii. Plans for handling missing data
- viii. Plans for addressing data limitations

1.3.2.2i Adverse Events Reporting:

- i. Procedures to be used to report adverse events to the Research Base, NCI, and/or FDA
- ii. Use current version of the CTC (must indicate the version number in protocol)

1.3.2.2j Consent Form:

Information on consent documents and templates are available at:
http://www.cancer.gov/clinicaltrials/understanding/simplification_of_informed_consent_docs/page21.3.2.2b Protocol Submission

The Research Base submits the protocol document to the Program and Information Office (PIO) of DCP. Research Bases should submit protocols electronically to NCI_DCP_PIO@mail.nih.gov. Attachments that are difficult to send electronically may be sent by mail:

U.S. Mail Address:

Protocol Information Office
Division of Cancer Prevention
National Cancer Institute

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9609 Medical Center Drive, RM 5E512
Bethesda, MD 20892-9786

Commercial Delivery Address:

Protocol Information Office
Division of Cancer Prevention
National Cancer Institute
9609 Medical Center Drive, RM 5E512 MSC 9786
Rockville, MD 20850

1.3.2.2k Protocol Review

Since public funds are used to support Research Base studies sponsored under NCORP Cooperative Agreement, no Research Base study using funds supplied under the Cooperative Agreement can be opened without prior approval from the NCI/DCP as communicated in approval letters sent to the Research Base Chair directly from the DCP Protocol Information Office. The Research Base also is not allowed to expend any NCI funds under this Cooperative Agreement to support any study disapproved by the NCI/DCP.

Purpose of the Review

The protocol review will focus on the inclusion in the protocol of all information and procedures necessary for conducting a successful study. Specific attention is paid to responses to concerns of the SSC and/or DCP conveyed to the Research Base at the time of concept approval. If the protocol differs from the concept in significant ways (e.g., change in endpoint, change in eligibility criteria), the Protocol Review Committee will review all aspects of the protocol to determine that the study has scientific validity and is feasible to conduct in the NCORP network.

1.3.2.2l Review Outcome

DCP will send all correspondence by email and/or mail regarding protocol reviews to: 1) Principal Investigator of the Research Base, 2) Study Chair, and 3) one other person designated by each Research Base to receive copies of correspondence related to all concepts and protocols under review at DCP.

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DCP sends results of protocol reviews within four weeks of the review meeting.

Protocol review letters can take one of four forms:

1. Protocol Approved
The PRC has determined that the protocol is ready for use in the NCORP network. The approval letter includes the credit assignment for the protocol (not applicable for cancer care delivery research).
2. Protocol Approval on Hold
NCI has determined that the protocol is suitable for conducting a study in the NCORP network and that no further changes are required to the protocol at the present time. However, further reviews and/or approvals by other components of NCI are required before DCP will issue a final approval. Examples include need for approval by a Central IRB or approval of plan for drug distribution for agents that will be distributed by NCI.
3. Revise and Resubmit
NCI has identified remediable problems that are outlined in a review letter. The investigators should review and respond to all the Committee's comments, change the protocol where necessary, and resubmit to the DCP Protocol Information Office as a revised protocol for further review. The review letter includes a date by which the revised protocol is due to DCP.
4. Protocol Disapproved
NOTE: Protocol disapproval is not common because approval of the concept indicated NCI's support for the proposed research. However, the Cancer Prevention and Control Protocol Review Committees reserve the right to disapprove a protocol,

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particularly when the protocol differs significantly from the approved concept.

1.3.2.2m After Approval

Research Bases must submit the activation date to PIO when the study opens.

The Research Base is responsible for communicating the results of the NCI/DCP review/evaluation process to relevant Research Base committees and members.

All pediatric study protocols (except phase 1 study protocols - although these may be included in the future) require approval by the NCI Pediatric CIRB **prior** to final approval of the study protocol document by NCI/DCP.

1.3.2.3 Protocol Amendment Development, Review, and Approval

1.3.2.3a Types of Amendments

- Scientific Amendments

Scientific amendments are those affecting the design or conduct of the study or those associated with safety of subjects. Examples of scientific changes include:

- i. Change in eligibility criteria
- ii. Change in sample size
- iii. Change in study evaluation, design, or analysis
- iv. Change in drug information
- v. Change in study chair or PI
- vi. Change in the informed consent
- vii. Any change to a protocol conducted under a DCP-sponsored Investigational New Drug Application (IND)

- Administrative Amendments

Administrative amendments are those not affecting the design or conduct of the study or affecting safety of subjects. The following are examples of administrative changes:

- i. Editorial changes only (that do not affect the design or conduct of the study)

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- and are not associated with safety of subjects)
 - ii. Addition or deletion of participating organization(s) unless this is a 'limited institution' protocol
 - iii. Change in name or contact information of study personnel (other than the study chair or principal investigator)
- Activation Amendments
Activation amendments are all amendments for changes in the protocol that occur between DCP approval and activation. They can be either scientific or administrative. They can incorporate changes requested or recommended in the DCP protocol approval letter in addition to other changes the investigators want to make.

1.3.2.3b Amendment Content

- 1) A cover letter must provide the rationale for each scientific change and an assessment of how that change will affect the conduct, outcome, and interpretation of the study
- 2) All changes (scientific and administrative) must be described in a point-by-point format (Change from:/Change to) and the changed protocol page(s) and section number(s) should be referenced
- 3) If an amendment will include both scientific and administrative changes, separate them within the amendment. Alternatively, submit separate amendments composed entirely of administrative changes or scientific changes
- 4) A marked copy of the revised protocol, clearly indicating newly added text (e.g. redlined) and deleted text (e.g. strikeout), must be attached
- 5) A clean copy of the revised protocol with consent document

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- 6) Title page of protocol indicates the date of the protocol amendment; if multiple dates are listed, one date must be clearly labeled NCI Version Date.
- 7) Document Submission Worksheet (DSW)

1.3.2.3c Amendment Submission

- 1) All documents must be submitted electronically to the DCP Protocol Information Office
(NCI_DCP_PIO@mail.nih.gov)
- 2) The Document Submission Worksheet must accompany every amendment and are available on the DCP PIO web page at: <http://prevention.cancer.gov/clinicaltrials/management/io/instructions>
- 3) Attachments that are difficult to send electronically may be sent by mail:

U.S. Mail Address:

Protocol Information Office
Division of Cancer Prevention
National Cancer Institute
9609 Medical Center Drive, RM 5E512
Bethesda, MD 20892-9786

Commercial Delivery Address:

Protocol Information Office
Division of Cancer Prevention
National Cancer Institute
9609 Medical Center Drive, RM 5E512 MSC 9786
Rockville, MD 20850

Questions regarding amendment submission procedures may be directed to the PIO at (240) 276-7130 or NCI_DCP_PIO@mail.nih.gov.

1.3.2.3d Amendment Review

All scientific amendments must receive approval from DCP prior to implementation.

1.3.2.3e Review Outcome

The PRC will determine one of two outcomes for each submitted amendment: **approval** or **disapproval**. All changes requested require

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approval for the amendment to receive approval.

The response letter will include reasons for disapproval for all disapproved amendments. The Research Base can revise disapproved amendments in response to PRC's comments and resubmit as new amendments.

NOTE: Research Bases must submit an Activation Notice for protocols that are activated as approved.

1.3.3 Conduct of Cancer Prevention and Control Clinical Trials and Cancer Care Delivery Research Studies

These procedures apply to cancer prevention, control and screening/post-treatment surveillance clinical trials as well as cancer care delivery research studies except as specifically noted.

Specific regulations regarding conduct of NCORP studies include the following:

1.3.3.1 NCI/DCP Approval Prior to Study Activation and Approval of Protocol Amendments

The Research Base has the responsibility for overseeing conduct of approved studies within its Network regardless of whether the study proposal originates from an investigator within or outside the Research Base.

Since public funds are used to support Research Base studies sponsored under NCORP Cooperative Agreement, no Research Base study using funds supplied under the Cooperative Agreement can be opened without prior approval from the NCI/DCP as communicated in approval letters sent to the Research Base Chair directly from the DCP Protocol Information Office (PIO). The Research Base also is not allowed to expend any NCI funds under this Cooperative Agreement to support any study disapproved by the NCI/DCP. In addition, all protocol amendments must be submitted to DCP's PIO and be approved by NCI/DCP prior to implementation. Depending on the nature of the amendment, the study may or may not be put on hold to further accrual and/or conduct until the amendment is approved.

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1.3.3.2 Use of the Adult and NCI Pediatric Central Institutional Review Board (not applicable for cancer care delivery research)

All U.S. institutions/sites participating in NCORP cancer control and prevention trials, as members of 1 or more Research Bases, are required to use the pediatric NCI Central Institutional Review Board for any NCORP trial under the pediatric NCI CIRB's purview. All NCTN treatment trials will use the Adult CIRB unless the site has access to an equivalent IRB.

The NCI may decide, at a future date, to mandate the use of additional NCI CIRB(s) for other types of NCORP trials.

1.3.3.3 Clinical Trials Reporting Program (CTRP)/clinicaltrials.gov Registration and Outcomes Reporting

All NCORP trials must also be registered and appropriate information updated in the NCI CTRP as described at:

<http://www.cancer.gov/clinicaltrials/conducting/ncictrp/main> as well as registered in the U.S. National Library of Medicine clinical trials database (i.e., at www.clinicaltrials.gov).

Changes in the trial design and accrual as well as results reporting from NCORP trials are also required to be reported in clinicaltrials.gov as required under the Food and Drug Administration Amendments Act (FDAAA), Section 801. The Research Base should ensure information on its NCORP trials is appropriately updated in these systems. Cancer care delivery research studies also may be reported in clinicaltrials.gov as appropriate.

1.3.3.4 Study Access (not applicable for cancer care delivery research)

Research Bases' member institutions/sites will be able to enroll patients on all adult phase 3 trials (and selected phase 2 trials) conducted by NCORP, irrespective of the specific Research Base which is leading the study.

Research Base phase 3 trials (including phase 2/3 studies) using funds supplied under this Cooperative Agreement cannot be conducted under a company IND; all phase 3 IND trials supported, in whole or in part, under this Cooperative Agreement must be conducted under a Research Base IND or a DCP IND. This also applies to phase 3 trials requiring an IDE.

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Phase 1 and phase 2 trials may be conducted under Research Base or company INDs or IDEs with appropriate monitoring per the Research Base data and safety monitoring plan or Data and Safety Monitoring Board (Data Monitoring Committee) policy for randomized phase 2 trials.

1.3.3.5 Agents from NCI/DCP Collaborators (not applicable for cancer care delivery research)

All NCORP studies using NCI/DCP-sponsored investigational agents under Collaborative Agreements (such as Cooperative Research and Development Agreements [CRADAs], Clinical Trial Agreements [CTAs], and Clinical Supply Agreements [CSAs]) must be conducted in accordance with the terms of the NCI/CTEP Intellectual Property Option to Collaborators, found on the CTEP website at:

http://ctep.cancer.gov/industryCollaborations2/intellectual_property.htm<http://ctep.info.nih.gov/industry/ipo.html>, and the NCI Standard Protocol Language for CRADAs and CTAs. When new avenues of cancer prevention or control involving any investigational agents are pursued, the clinical information obtained in the study should be acceptable to the FDA and other health authorities for inclusion in a possible licensing application. When NCI/DCP and the Research Base contract with the same company (or companies) for support for the same trial (i.e., trials conducted under a NCI/DCP Collaborative Agreement, the Research Base contracts may require review by the appropriate DCP program at the discretion of NCI (see Part 4 – Appendices - Section I.F. in these Guidelines).

1.3.3.6 NCORP Investigational Agent Development and Regulations

(not applicable for cancer care delivery research)

The clinical development of new cancer preventive agents is an important use of Research Base resources. The Research Bases are a vital component of the research apparatus necessary for the clinical development of new investigational agents. NCI/DCP Program Directors (working as needed with other NCI program staff members) will advise investigators of specific requirements and changes in requirements concerning investigational drug management that the FDA may mandate.

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NCI/DCP and NCI/DCTD staff will review general policies and procedures periodically, as needed, and provide advice regarding mechanisms established by the Research Bases to meet FDA regulatory requirements for studies involving DCP-sponsored investigational agents.

1.3.3.7 NCORP Required Tools and Services

Research Bases are **required** to use standard NCORP tools and services for all NCORP trials including, but not limited to: (a) NCTN information system for tracking biospecimen collection from NCTN trials (in development); (b) the NCI Common Terminology Criteria for Adverse Events (CTCAE); and (c) review of all pediatric phase 2 and phase 3 trials by the NCI Pediatric Central Institutional Review Board (CIRB). NCORP Cancer Center Research Bases are expected to use the tools and services by the end of the initial five year funding cycle. Research Bases also will be required to implement standard NCORP data collection tools approved by the NCORP cancer care delivery Coordinating Committee should any be instituted during the NCORP award period.

During the approval process for study protocols and amendments, NCI/DCP ensures that standard NCORP tools and services are used. DCP Cancer Center Research Bases are expected to use NCI tools by the end of the initial five year funding cycle. In addition, Research Base trial protocols will be periodically audited by NCI/DCP to ensure that the tools related to common data elements in compliance with NCORP approved sections of the data dictionary for common data elements in caDSR are used in the data collection instruments for NCORP trials.

It is strongly encouraged that the Cancer Trials Support Unit (CTSU) be utilized for all NCORP trials. NCORP trials using CTSU must also use the NCTN Oncology Patient Enrollment Network (OPEN) and Regulatory Support Services (RSS) for central registration and randomization of patients onto NCORP trials. It is anticipated that all cancer prevention, screening/post-treatment surveillance and control trials will be available on the CTSU at the end of the initial five year funding cycle.

1.3.3.8 Data Management

The Research Base should establish data management policies and procedures for ensuring data accuracy,

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timeliness, completeness, and consistency for NCORP studies. The general categories that should be addressed by the data management policies are listed below:

- Central storage, security, processing and retrieval of study results that incorporates security features consistent with DHHS guidelines.
- Procedures for backing up the Research Base's clinical and administrative data, including intermittent duplication of the database with storage at a remote facility.
- Protection of participant confidentiality at all steps in the submission and analysis of participant data, including the technical integrity and security of participant information in compliance with federal regulations, such as the Health Insurance Portability and Accountability Act (HIPPA).

1.3.3.9 CDUS/CDS Reporting (not applicable for cancer care delivery research)

In addition, data must be submitted in a timely manner on all NCORP trials, as appropriate, to the NCI/DCTD Clinical Data Update System (CDUS/CDS) at http://ctep.cancer.gov/protocolDevelopment/electronic_applications/cdus.htm. Reporting will generally consist of CDUS abbreviated data (primarily demographic and accrual). The Research Base should coordinate activities to ensure information on its NCORP trials is appropriately updated in all these systems.

1.3.3.10 Collection and Transmission of Data and Biospecimens

All data, as well as any biospecimens collected for an NCORP study must be sent by the institutions/sites participating in the study to the Research Base that is leading the study, unless an exception is approved by the NCI/DCP to accommodate the needs of a specific study. The Research Base is responsible for overseeing the timely collection and transmission of data and biospecimens from all its member institution/sites to NCORP studies for patient accruals that are credited to the Research Base. Collection and banking of tissues and other biological specimens is an increasingly important aspect of the clinical research performed by the Research Bases. For NCORP trials that it leads, the Research Base is responsible for coordinating the acquisition and shipping of

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protocol-specified tumor specimens and biological fluids (with relevant clinical data) to the appropriate laboratories for testing and to a tumor/specimen repository for storage of specimens for future correlative science laboratory studies. The Research Base is also responsible for ensuring that all its members submit required biospecimens for NCORP studies when the Research Base is credited with the accrual even if the Research Base is not leading the trial.

1.3.3.11 Data Reporting

The Research Base must have policies and procedures in place to ensure that data reporting requirements are fulfilled in a timely manner including the major data reporting requirements outlined below.

- Report of Studies: The Research Base is responsible for providing a semi-annual Report of Studies on all Research Base studies. The Report of Studies should include information detailing participant accrual and demographics, data timeliness, toxicity experienced by study participants, and other items as appropriate, including outcome data as appropriate. The Research Base is responsible for ensuring that electronic copies of the Report are available to NCORP Network members and to the NCORP Director. If a Research Base determines that a Report of Studies is not needed biannually, it must seek approval from the NCORP Director, providing the rationale for this request in writing.
- NCI Access to Research Base Website and Data Files Requested by NCI: The Research Base is responsible for ensuring that the NCORP Director and Associate Director have access to the Research Base website, including the member side of the website.

Upon request by the NCI, the Research Base is also responsible for providing true copies of data files and supporting documentation for specific NCI-supported trials and other studies in a timely manner.

- Data for Member Performance Evaluations, Audits, & Data Monitoring Safety Boards (DSMBs): The Research Base is responsible for providing accurate and timely reporting of data on accrual, data timeliness, and accuracy, protocol compliance, long

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term participant follow-up, and audit results related to the conduct of Research Base clinical trials and other studies by member sites for Performance Evaluations of the sites. The Research Base will also provide all data required for member site auditing as well as data evaluation of trials for the Research Base's Data and Safety and Monitoring Board.

**1.3.3.12 DSMB/DMC Recommendations for NCORP Studies
(not applicable for cancer care delivery research)**

The Research Base is required to send a listing (or an email with internet access link to a listing) of all Data and Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) recommendations accepted by the Research Base Chair(s) to the NCORP Director after every scheduled DSMB/DMC meeting. DSMB/DMC recommendations accepted by the Research Base Chair(s) after ad hoc DSMB/DMC meetings/calls must also be communicated to the NCORP Director.

1.3.3.13 Adverse Event Reporting and Patient Safety

At present, sites are not able to submit expedited AE reports through AdEERS for studies without an agent/device/surgery/radiation. The study must have at least one of those intervention types. So at present, behavioral or cancer care delivery research studies are not accommodated in ADEERS or AERS.

The Research Base must establish a system for assuring expedited reporting of all serious adverse events to ensure potential patient safety issues can be identified and addressed quickly. Adverse events should be reported using the Common Terminology Criteria for Adverse Events v4.0 (CTCAE) or most recent version, which is NCI standard language for reporting adverse events in oncology clinical trials and is provided on the NCI/DCTD/CTEP website at: <http://ctep.cancer.gov/reporting/ctc.html>.

For agents under DCP-sponsored INDs, this involves reporting to DCP via the Adverse Event Expedited Reporting System (AdEERS), or its successor application, according to the guidelines specified in each protocol. Research Bases must also use AdEERS, or its successor application, for expedited reporting of serious adverse events for all NCORP trials (even those not under a DCP IND or not under any IND/IDE) since

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AdEERS provides reporting pathways for studies that do not include DCP IND agents, as well as pathways for studies that do not include any agents (e.g. surgical only study, radiation only study). Expedited reporting using AdEERS should be performed as described at:

http://ctep.cancer.gov/protocolDevelopment/electronic_applications/adeers.htm. Serious adverse event reporting for all NCORP trials should also follow the "NCI Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD (CTEP and CIP) and DCP INDs and IDEs" available at: http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf

In addition, for any study using agents under a DCP-sponsored IND, any increase in the incidence of expected toxicities and any plans to change a trial design or close a trial early due to toxicity should immediately be discussed with DCP before any action is taken. For NCORP studies that are not being conducted under a DCP IND, any major patient safety issues (e.g., study closure/suspension for adverse events, inappropriate randomization of patients to treatment arms, etc.) also require immediate notification to DCP before any action is taken.

In general, for studies with these types of immediate safety issues that are under monitoring by a Data and Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) as defined in Part 1: Section IV.B.1.5.6, immediate notification should be made to the DSMB/DMC Chair and the NCORP Director. Immediate notification for studies not under DSMB/DMC monitoring should be made to the NCORP Director.

1.3.3.14 Early Trial Closure

The Research Base must establish policies and procedures for early closure of studies in conjunction with the associated DSMB. The Research Base should explicitly describe the policies in place for phase 2 and phase 3 studies. Statistical guidelines for early closure should be presented as explicitly as possible in the protocol in order to facilitate decisions regarding early closure. NCI/DCP have approved early stopping guidelines for slowly-accruing phase 2 and 3 studies for NCORP. If accrual is behind expectations for a specific study, the Research Base should involve the appropriate NCI/DCP and DCCPS staff in discussions

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about possible ways to enhance accrual in order to avoid study closure.

Procedures regarding notification of DCP about early study closure are outlined below and should be incorporated into the Research Base's policy for study closure. These procedures also apply to major modifications to study design and to suspension of study accrual and/or intervention (e.g., suspension due to patient safety issues) for any NCORP trial, regardless of whether it is under DCP IND or not.

Early Stopping Rules for Slowly-Accruing Studies (Phase 2 and Phase 3) (not applicable for cancer care delivery research)

The following early stopping guidelines for slowly-accruing phase 2 and 3 studies conducted under NCORP are stated in terms of the percentage of projected accrual during specified quarters after activation. For example, Quarter 5-6 accrual signifies the number of patients enrolled on study during Quarters 5 and 6 after activation, divided by the number of patients that were projected to be enrolled during that time period based on the accrual rate specified in the protocol.

These guidelines apply only to phase 2 and 3 trials that have not had a formal interim efficacy analysis presented to the Data and Safety Monitoring Board (DSMB) before the end of the 6th quarter from study activation.

Guidelines (not applicable for cancer care delivery research): If Quarter 5-6 accrual is $\leq 20\%$ of projected, the Research Base is strongly encouraged to stop the study. In extraordinary circumstances the DCP Program Director for the Research Base can agree to accept for review an amendment to change the accrual goals or to change the protocol with the intent of increasing accrual.

If Quarter 5-6 accrual is $< 50\%$ and $> 20\%$ of projected, then the study team has 6 months to improve accrual.

If Quarter 8 accrual is $< 50\%$ of projected, then the research base should submit an amendment to DCP PIO to reflect actual accrual. The investigators should consider including scientifically valid changes to the amendment intended to increase accrual. The

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implications of the new accrual rate on study relevance and feasibility should be discussed in the proposed amendment.

Implementation (not applicable for cancer care delivery research): Protocols submitted to DCP for review must include an estimate of planned accrual rate. The DCP Cancer Prevention and Control Protocol Review Committee will review this estimate with regard to how realistic the estimate is and the relevance of study results at the end of the planned accrual time.

As soon as the Quarter 5 and 6 accrual figures become available, the Research Base will provide to DCP PIO average accrual for Quarters 5 and 6, projected accrual for Quarters 5 and 6 from the protocol, total accrual Quarters 1 to 6, and projected accrual for Quarters 1 to 6 from the protocol. The Research Base Chair will either close the trial or notify the investigators that they have another 6 months in which to improve accrual according to the guidelines described above.

Amendments that include changes related to low accrual as determined by the accrual reports from Quarters 5 and 6 or Quarter 8 (see previous paragraphs) must identify these guidelines as the basis of the amendment and should include background information describing the actual accrual compared to the projected accrual, potential reasons for the slow accrual, explanations for expecting changes to increase accrual (if applicable), and an explanation for the relevance of the study given new accrual goals. The DCP Cancer Prevention and Control Protocol Review Committee will consider this information when reviewing the amendment.

For studies that are closed or amended, the Research Base will notify the Group Data and Safety Monitoring Board (DSMB) of the closure or amendment at their next regularly scheduled meeting. Research Base chairs may consult with their DSMB regarding the decision for early closure, if desired. In the unusual circumstance that the Research Base Chair believes that the guidelines are inappropriate for a given study, he or she will initiate a discussion with the responsible NCI Program Director to reach a joint decision concerning what course to take.

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1.3.4 Quality Assurance and Onsite Auditing

The Research Base is responsible for establishing mechanisms to assure the accuracy and reliability of the Research Base's study data. Quality assurance is a complex undertaking spanning the entire range of studies conducted by the Research Base including but not limited to: observational, survey research, registry, administrative, screening/post-treatment surveillance, biomarker, omics, diagnostic, interventional, and imaging. Key items that should be addressed in a Research Base's quality control procedures include the following:

1.3.4.1 Study Monitoring

The Research Base is responsible for overall organization and oversight of study teams that monitor data from specific research studies. All research carries with it an obligation to ensure optimal therapy for participating patients, providers and organizations and optimal conduct of the research such that the participation is meaningful. Accurate and timely knowledge of the progress of each study is a critical Research Base responsibility. The elements described below are considered essential for study monitoring:

- Precise tracking of participant accrual (both eligible and ineligible participants) and adherence to protocol-defined accrual goals. In the event that the Research Base wishes to continue accrual to a study beyond the protocol-specified total accrual goal for eligible and ineligible participants, the Research Base must seek approval from DCP prior to continuing accrual
- Ongoing assessment of participant eligibility, participant evaluability, and appropriate assignment of participants to study groups (e.g., randomization)
- Adequate measures to ensure timely submission of study data as well as adequate measures to ensure timely medical review and assessment of individual patients' data with rapid reporting of treatment-related morbidity information and measures to ensure communication of this information to all appropriate parties
- Interim evaluation of outcome measures and patient safety analyses

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- Tracking of response rates, including those respondents that either decline or could not be found, those that responded, and oversight and monitoring of missing data
- Ongoing quality assessment and oversight of program characteristics, patterns of care data and organizational policies and providing data to the NCORP-wide repository.

Study monitoring reports describing accrual and demographics, data timeliness, toxicity, and other items should be prepared as appropriate for Study Chairs, for Data and Safety Monitoring Boards (DSMBs), and for inclusion in the semi-annual Report of Studies.

1.3.4.2 Member Performance Evaluations

The Research Base is responsible for oversight of all its members (i.e., Community sites, Minority/Underserved Community Sites, and other member institutions) including placing members on probation for inadequate performance and for removing them from the Research Base if performance is not adequate during the probationary period or at any time during which the participating site does not meet established Research Base standards. Performance factors to be considered include the following:

- Accrual of adequate number of eligible patients onto NCORP trials;
- Accrual of adequate number of eligible participants onto cancer care delivery research studies;
- Timely and accurate submission of required data;
- Conscientious observance of protocol requirements;
- Compliance with regulatory requirements for the protection of human subjects and Good Clinical Practice;
- Participation in study development, leadership, and publication; and
- Participation in Research Base leadership and/or other Research Base activities; and
- Summary reports of the results of performance evaluations

1.3.4.3 Training Program

The Research Base should have training activities that address data collection, data management, and overall data quality, including but not limited to the following areas:

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- Training of new Clinical Research Associates (CRAs) in the Research Base's data submission policies and ongoing training of all CRAs concerning changes to Research Base procedures and instructions for data submission in new protocols;
- Instruction of Study Chairs on their responsibilities for study monitoring;
- Instruction of Principal Investigators and other investigators at member participating Sites on their responsibilities for complying with Research Base SOPs, including conflict of interest and all other federal regulations at their institution/site and any additional site(s) for which the member site has oversight responsibility; and
- Training/guidance provided to all participants on how to comply with NCI/NIH policies and procedures (e.g., policies regarding human subjects protection, ethics, conflict of interest, and procedures such as those regarding use of the CTSU), in addition to the policies and procedures of other governmental agencies (e.g., OHRP, FDA) that are also important to the conduct of NCORP studies.
- Training /guidance provided to all participants on the breadth, specificity and the quality of cancer care delivery research data from hospital registries, organizations, medical records, financial and administrative data, and delivery characteristics, as well as the ability to relate these databases and incorporate core data elements.

1.3.4.4 Central Review and Scientific Research Committees

Research Bases should either develop or utilize established Committees for conducting central review of the major elements that affect the outcome of cancer prevention and control studies or provide integral/integrated translational science associated with specific trials, including the following:

- *Integral or Integrated Correlative Science and/or Translational Research Committees:* integral and/or integrated correlative science or translational science studies included in NCORP Research Base studies that address specific and important scientific hypotheses (or are integral to the primary study design) should be appropriately designed. Funding for these studies is not provided directly by NCORP award but may be applied for via BIQSFP funding.
- *Pathology:* Pathology review may be either by a committee within the Research Base Cancer Centers associated NCTN Network Group, or by an

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external reference panel. Prospective central verification of pathologic diagnosis may be required for specific trials in which it is integral or essential to the study design (i.e., cases in which known variability in the accuracy of histologic (or other) diagnosis is a potentially serious problem and in which pathology data is integral to appropriate study design and analysis). Funding for this central review, whether retrospective or prospective, is not provided by NCORP award; however, it can be provided via BQSF funding.

- *Imaging support including diagnostic imaging:* When relevant, central review (either prospective or retrospective) of imaging in NCORP trials may be required for evaluating response, establishing a diagnosis, and/or screening of patients and should be provided via coordination with the Research Base's (or associated NCTN Network Group's) Radiotherapy and Imaging Core Services Centers.
- *Systemic Interventions (Chemotherapy or other Biologic Agents):* Central review may be performed by the Research Base study team for the trial to determine protocol compliance with dose administration and dosage modification.
- *Surgery:* When relevant, adequacy of protocol-specified surgical procedures may be assessed (e.g., through review of operative notes, study-specific surgical forms, and pathology reports) by the Network Group study team for the trial.
- *Legacy Large Cancer Prevention Trials:* In some cases, there may be a separate structure for the review of data and correlative studies in large legacy cancer prevention trials.

Research Bases should develop Committees for conducting central review of cancer care delivery research studies and interface with the Cancer Care Delivery Research Coordination Committee to, review infrastructure development of affiliated sites, determine study needs, and allocate resources. Cancer care delivery research Committees may include:

- *Observational data committee:* As appropriate for the study, review of study research design and questions related to primary data from surveys, focus groups or interviews with participants or secondary participant data from registry, patterns of care, medical record data, and financial and other administrative data.

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- Interventional data committee: As appropriate for the study, review of study research design and questions related to the collection of prospective data where the purpose is to introduce interventions into the delivery system. Prospective data could be collected from patients, clinicians or organizations, when essential to intervention study design.
- Financial Data committee: Review of study research design and questions related to the collection of financial data related to study objectives.

1.3.4.5 Onsite Auditing

The NCORP Research Base has responsibilities with respect to onsite auditing. In particular, the Research Base should ensure that policies and procedures are in place to ensure that auditors participating in the onsite auditing program maintain confidentiality of all participant materials.

Information on the requirements for onsite auditing is provided by Guidelines from the Clinical Trials Monitoring Branch (CTMB) of NCI/DCTD/CTEP available at:

http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_coop_ccop_ctsu.htm

In order for the NCI to review the Research Base's compliance with this requirement, each Research Base should provide annually an accounting of audit activities for all its members (see the Suggested Format for Reporting Onsite Auditing Activities in Part 4 – Appendices – Section II.A.9).

CTMB also provides direct oversight of each Research Base's auditing program. The purpose of an audit is to document the accuracy of data submitted to the Research Bases and to verify investigator compliance with protocol and regulatory requirements. In addition, the monitoring program provides an opportunity for the audit team to share with the staff at the participating site information concerning data quality, data management, and other aspects of quality assurance. The main objective of the audit program used by the Research Bases is to verify study data that could affect the interpretation of primary study endpoints. This is done through independent verification of study data with source documents.

The Research Base is responsible for oversight of all its members enrolling patients on NCORP studies that any

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member credits to the Research Base regardless of whether the Research Base is leading the study or not. This includes ultimate oversight responsibility for Community and Minority-Underserved Community site members as well as affiliates when accrual for an enrollment in an NCORP trial is credited to the Research Base. The Research Base should be aware of all affiliate sites participating in its studies under the aegis of an institutional member, Community site, or Minority-Underserved Community site via its consolidated roster. Any members of a Research Base found not to be in compliance with the NCI Guidelines for Onsite Monitoring by the CTMB may be suspended from participating in any NCORP trials until a corrective action plan is submitted by the institution/site to the Research Base and is reviewed and approved by the Research Base and DCP.

Additional information on quality assurance required of Research Bases with respect to trial data and, in particular, procedures a Research Base is required to follow in the event any data irregularities are identified through the audit program or other quality control procedures are explained in detail in these Terms and Conditions of Award. Please see Part 1 - Section IV.D.4 of these Guidelines on Quality Assurance regarding reporting of audit issues and potential cases of scientific misconduct.

With respect to cancer care delivery research, the audit requirements will be defined by the Cancer Care Delivery Research Coordination Committee.

1.3.5 Financial Management

The Research Base is responsible for its own financial management, including appropriate funding for all Research Base activities and provision of funding to member institutions/sites through purchase service agreements or subcontracts as well as funding for other important scientific and administrative services needed for Research Base functions such as support for Study Chairs and Scientific Research Committee Chairs.

Each Research Base's clinical trials protocol approved by NCI for Community or Minority/Underserved Community Site and/or affiliate institution use will be assigned a credit value by NCI/DCP (credits do not apply to cancer care delivery research studies). The credit assignment will be detailed within the protocol approval letter. Credits will be based on the complexity of the intervention, the amount of data management required, and the duration of follow-up. The

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credit is a one time credit claimed by Community or Minority/Underserved Community Site grantees' against the grant year in which the participant was enrolled on the protocol. A follow-up credit can be claimed one time per year for each year that there is an intervention (i.e., chemo-preventive agent and/or placebo administered) starting the year after the participant was enrolled.

Non-NCORP institutions will receive per case reimbursements for accruals to cancer prevention and control trials from the Research Bases.

A new Research Base applicant is expected, during its initial competitive segment (project period), to develop a menu of cancer prevention and control protocols that will allow the Research Base to meet the credit minimums per year in its subsequent competing segments.

The Research Base should ensure that funding is allocated at the site so that investigators and research staff from different departments and disciplines at the institution that participate in NCORP studies are appropriately represented in the disbursement of funding. For example, the Principal Investigator(s) at an institution/member site, with which a Research Base has a subcontract or purchase service agreement (PSA) for work related to enrollment of patients and conduct of studies in NCORP, may be a member of the Medical Oncology department at the institution, yet work under the subcontract or PSA which is performed across multiple departments at the institution (e.g., surgery, pathology, radiation oncology). The Research Base should strive to ensure that all member institutions/sites distribute funding to all departments involved in support of NCORP studies in a manner that reflects the work performed by the various members of the research team.

Any separate, non-NCI/DCP funding (i.e., funding not provided under the Cooperative Agreements of NCORP) dispensed by a Research Base to cover costs associated with participant enrollment on NCORP studies that it leads must be provided to all qualified institutions/sites that participate in its NCORP studies regardless of which Research Base the enrolling institution belongs to and/or applicable credits with the patient clinical trial accrual. This principle is considered an essential feature of NCORP and the Terms and Conditions of Award as it is fundamental to ensure fairness for work performed across the Network.

1.3.6 Legacy Studies

Legacy studies supported by the Community Clinical Oncology Program will be conducted under the same Terms and Conditions of Award as NCORP studies. Hence, the awardees

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of any of the key components of NCORP (i.e., NCORP Research Bases, NCORP Community Sites, and NCORP Minority-Underserved Community Sites) are bound by the Terms and Conditions of their Award under NCORP when working on legacy studies that are supported by NCORP.

1.4 Program for Collaborations and Participation in Collective Management

NCORP Research Bases are responsible for developing collaborations with other Research Bases as well as other NCI-sponsored programs and investigators (e.g., Cancer Centers, R01/P01 investigators, NCI Cancer Research Network) to augment and enhance the clinical and cancer care delivery research strategy and research productivity of its portfolio of studies conducted in NCORP. In addition, the Research Base is also responsible for participating in the collective management of the NCORP Network including participation in appropriate NCORP Program activities and initiatives (e.g., NCI Scientific Steering Committees, NCI CIRB, etc.) and through the NCORP Leadership Management Committee by making recommendations to NCI for modifications to the Program as well as to standard NCORP common tools and services. Finally, the NCORP Research Bases are expected to cooperate in any program evaluation processes that are conducted including interacting with NCI representatives in coordinating the evaluation.

NCORP Research Bases will participate in the Cancer Care Delivery Research Coordinating Committee which will be comprised of representatives from NCI, all Research Bases and select Community Sites. The Committee will develop a scientific agenda and priorities for cancer care delivery research within the NCORP network, cancer care delivery research identify and develop common data elements to support the scientific plan (including program characteristics and patterns of care data), develop a training plan for sites to assess and enhance data collection capabilities, and develop a protocol which defines cancer care delivery research auditing requirements. The Cancer Care Delivery Research Coordinating Committee will have access to NCORP-wide repository information from NCORP Community Sites and Minority/Underserved Community Sites (e.g., cancer registry data, processes of care data and data on organizational characteristics and policies). All NCORP components are expected to comply with decisions and recommendations of the Coordinating Committee.

Each Research Base is required to have policies to encourage other Research Bases to name co-principal investigators for studies that the Research Base leads (in areas that other Research Bases have scientific research goals and/or scientific research committees) in order to augment accrual and participation in NCORP trials and cancer care delivery research.

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1.5 Compliance with Federal Regulations for Clinical Research & Resource Sharing Plans

The Research Base is responsible for assuring that the Research Base and its member sites are in compliance with all applicable federal regulations concerning the conduct of human subjects research. Policies and guidelines to be addressed include the following:

1.5.1 Office for Human Research Protection (OHRP) Assurances

The Research Base must assure that each member (this includes all affiliates or participating sites enrolling participants under any of the membership categories for the Research Base) has a current, approved Federal wide Assurance (FWA), on file with OHRP. Information on assurances is available on the OHRP website at: <http://www.hhs.gov/ohrp/>. In addition, federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

1.5.2 IRB Review of NCORP Studies by Member Institutions/Sites

The Research Base must assure that each protocol for an NCORP trial that one of its member institutions/sites credits to the Research Base is reviewed and approved by the appropriate Institutional Review Board (IRB) of the Research Base member prior to patient entry via the Regulatory Support Services (RSS) of the CTSU, and assure that each protocol is reviewed annually by the IRB so long as the protocol is active (it is anticipated that the adult or pediatric NCI CIRB will be the IRB of record in most cases). The Research Base must ensure that each member site forwards its regulatory documents to RSS, otherwise the site will not be allowed to enroll patients on NCORP trials.

1.5.3 Assurance of Appropriate Informed Consent by Member Institutions/Sites

The Research Base must have procedures in place to ensure that each member institution/site is trained and understands the policies and procedures relevant to ensuring that participants are enrolled on studies with appropriate informed consent per NCI/NIH policy and federal regulations. The template for the NCI informed consent document must be used for all NCORP trials, with appropriate modifications as approved by NCI/DCP for specific trials during the protocol development and review process. Information on the NCI informed consent templates is available at: <http://cancer.gov/clinicaltrials/patientsafety/simplification-of-informed-consent-docs/page3>.

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1.5.4 IRB Review of the Research Base

Institutional Review Board (IRB) review of the Research Base grant is required. The IRB should be able to review not only clinical trial but also cancer care delivery research. The IRB should determine and document that the Research Base has sufficient mechanisms in place to ensure that (1) oversight of data management and analysis and that Data Safety and Monitoring systems are adequate, especially with respect to promoting the confidentiality of patient data, given the nature of the research involved; (2) sample protocols and informed consent documents are developed and distributed to each member institution/site participating in a study; (3) each member institution/site holds or is covered under an applicable OHRP-approved Federal wide Assurance (FWA); (4) each protocol is reviewed and approved by the IRB covering the member institution/site prior to the enrollment of participants; (5) any substantive modification by the institutional member/site of sample consent information related to risks or alternative procedures is appropriately justified; and (6) informed consent is obtained from each participant in compliance with DHHS regulations. Information on this requirement for IRB review can be obtained on the OHRP website at: <http://www.hhs.gov/ohrp/>.

1.5.5 Inclusion of Women, Minorities, and Children in Clinical Research

NIH policy requires that women and members of minority groups and ethnic subgroups be included in all NIH-supported research projects involving human subjects at: http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Compliance with this policy requires appropriate study designs, targets for total protocol accrual with distribution by ethnic/racial categories and by sex/gender, as well as reporting of accrual by ethnic/racial categories and by sex/gender. Since Research Bases conduct multiple phase 3 clinical trials, the amended NIH Policy on inclusion of women and minorities in research also applies (see NIH Guide Notice on NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>, with a complete copy of the updated Guidelines available at: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. A description of plans to conduct analyses, as appropriate, by sex/gender and/or ethnic/racial groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports.

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Note: A Research Base should report this data for all patients enrolled on studies it leads regardless of whether it is credited with the patient enrollment or not and this data should be reported in the Research Base annual progress reports. Final analyses of sex/gender and ethnic/racial differences must be reported in the required Final Progress Report or any future competitive renewal applications.

NIH policy requires that children (i.e., individuals under 21 years of age) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them as described at: <http://grants.nih.gov/grants/funding/children/children.htm>. For cancer clinical research, Research Bases conducting research in adult cancers can provide a rationale for not including children because the majority of children with cancer in the United States are already accessed by a NCTN Network Group devoted to pediatric cancer research, so that requiring inclusion of children in the proposed adult study would be both difficult and unnecessary (since the research question is already being addressed in children by the pediatric network) as well as potentially counterproductive since fewer children would be available for the pediatric Network study if other studies were required to recruit and include children. This does not apply to cancer care delivery research, children may be included in cancer care delivery studies if appropriate to answer the research question(s).

1.5.6 Data and Safety Monitoring Policy and Plans (does not apply to cancer care delivery research)

The Research Base must establish a Data and Safety Monitoring Policy for the clinical trials conducted by the Group in compliance with NIH and NCI guidelines for data and safety monitoring for clinical trials. Data and Safety Monitoring Boards (DSMBs) or Data Monitoring Committees (DMCs) must be established that comply with the "NCI NCORP Program Data Monitoring Committee Policy" as provided in Part 4 – Appendices – Section VIII. For the purposes of these Guidelines, the terms DSMB and DMC are used interchangeably to refer to committees established under with this policy. The DSMB/DMC must be used to monitor all phase 3 trials and randomized phase 2 trials led by the Research Base. The Research Base's DSMB/DMC policy and membership roster, as well as any changes/modifications to the policy or membership roster, must be submitted to and approved by the NCORP Director.

Monitoring Plans for Trials Not Under DSMB/DMC: Data and Safety Monitoring plans developed for other NCORP Research Base studies (e.g., phase 1 and phase 2 studies, pilot studies, etc.) must comply with the NIH policy for data and safety

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monitoring, posted on the NIH website at:
<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>, with additional description at:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>. Further information concerning essential elements of Data and Safety Monitoring Plans for clinical trials funded by the NCI is available at:
<http://www.cancer.gov/clinicaltrials/conducting/dsm-guidelines>.

1.5.7 Resource Sharing Plans

1.5.7.1 Data Sharing Policy

The NCORP Research Base is required to have a plan for sharing research data. Information on the NIH policy regarding sharing research data can be found on the NIH website at:

http://grants.nih.gov/grants/policy/data_sharing.

The Research Base's policy for data sharing must be submitted to and approved by the NCORP Director. A template to help Research Bases develop their own Data Sharing Policies is provided in Part 4 – Section VII of these Guidelines. Per this policy, requests for data will only be considered once the primary study analyses have been published.

Requests for data from clinical trials, conducted under a binding collaborative agreement between NCI/DCP and a pharmaceutical/biotechnology company, that are not under DSMB monitoring but are not yet subject to the Data Sharing Policy (e.g., because the primary study analyses have not yet been published) must be in compliance with the terms of the binding collaborative agreement and must be approved by NCI/DCP (i.e., the NCORP Director and for cancer care delivery research studies, the Associate Director, in conjunction with the NCI/DCTD Regulatory Affairs Branch). Release of data may also be subject to the terms of any contracts the Research Base has with other entities which cover any of the requested data.

1.5.7.2 Biospecimen Sharing Policy

The Research Base is required to follow the NCI/DCP policy regarding review of requests for use of banked biospecimens collected in association with NCORP trials that it leads by DCP's Protocol Review Committee or an NCI/DCTD-approved NCTN Correlative Science Committee as described

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in Part 1 – Section IV.C.3. Research Bases are also required to have a plan/policy in place to describe how information on its inventory of biospecimens will be made available to the public that is submitted to and approved by the NCORP Director and the Lead NCTN Program Director, Associate Director Cancer Diagnosis Program, and Program Director of the Tumor Banking Program for the Network Groups. This inventory should be consistent with standards established by the Network Tumor Banking Committee for the NCTN Program.

Research Bases having legacy prevention trials must have policies in place for review and approval for requests for use of specimens in research studies.

Research Bases should also have plans in place regarding the following types of resources, as appropriate for the clinical research it conducts: [Sharing Model Organisms](#) and [Genome Wide Association Studies \(GWAS\)](#).

1.5.8 *Education on the Protection of Human Subjects*

NIH policy requires education on the protection of human subject for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. This policy is available on the NIH website at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

1.5.9 *Other Federal Regulations*

The [NIH Public Access Policy](#) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive [PubMed Central upon acceptance for publication](#). To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication. More information about this policy or the submission process is available on the NIH Public Access Policy website at: <http://publicaccess.nih.gov/>.

Information on other federal regulations (and their associated citations/URLs) that may be applicable to the Research Base's research is provided in Part 4: Appendices – Section IV.B.

1.6 *Conflict of Interest Policy*

NCORP Research Bases receiving NIH funding from a grant or cooperative agreement must establish a Conflict of Interest Policy that is in compliance with all of the DHSS regulatory requirements for

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conflict of interest as outlined by NIH grants policy available at: <http://grants.nih.gov/grants/policy/coi>. This policy should ensure that there is no reasonable expectation that any investigator or staff member of the Research Base or at any of its member institutions/sites involved in the design, conduct, or reporting of research will be biased by any conflict of interest (using the definition of investigator provided in the NIH grants policy).

1.7 *Special Requests for Use of NCORP Infrastructure Services*

The infrastructure of NCORP, including NCI/DCP and NCI/DCCPS supported contract services, can only be used for NCORP studies approved by NCI/DCP under this Cooperative Agreement. In special circumstances, a Research Base may request limited use of certain services (e.g., regulatory support services (RSS), the Oncology Patient Enrollment Network (OPEN) for a related research effort or study such as a banking protocol not associated with a specific NCORP clinical trial that is supported by charitable funds or a related oncology research study funded by another NIH-funded program). These requests must be reviewed and approved by NCI/DCP and NCI/DCCPS via an official written approval by the NCORP Director and NCORP Associate Director. In addition, any special request for use of NCORP infrastructure services for cancer care delivery research studies (e.g. studies sponsored through the Department of Veterans of Affairs) also must be approved by the NCORP Director and Associate Director. It is expected that only requests that are compatible with and are anticipated to benefit the overall research goals of NCORP would be approved, subject to the availability of NCORP resources/funding, since the use of the requested services are funded under NCORP.

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2. Specific Awardee Rights & Responsibilities – NCORP Community Sites

These procedures apply to both cancer prevention, control and screening/post-treatment surveillance clinical trials as well as cancer care delivery research studies except as specifically noted.

2.1 Definition, Eligibility, and Accrual Threshold

Throughout these Terms and Conditions of Award, "NCORP Community Site" refers to the organizational structure which is composed of the key personnel (including the scientific and administrative leaders at the Site) responsible for implementing NCORP studies and collaborating on research goals of NCORP with NCORP Research Bases. In addition, throughout these Terms and Conditions of Award, "NCORP Community Site," refers to the main community site as well as any component and sub-component site(s) included in the award if the Community Site provides complete management services for the component and sub-component site(s) related to enrolling patients on NCORP studies.

2.1.1 Definition of an NCORP Community Site

An NCORP Community Site is defined as a consortium of community hospitals and/or oncology practices or a community-based integrated healthcare system that accrue participants to: 1) cancer prevention, control and screening/post-treatment surveillance clinical trials designed and conducted by NCORP Research Bases; 2) NCTN-sponsored cancer treatment and imaging trials, as well as quality of life studies embedded within them; and 3) cancer care delivery research studies (where "participants" can be defined as patients, clinicians, and/or healthcare organizations). NCORP Community Sites will also develop and enhance their data collection and study implementation capabilities related to cancer care delivery research, provide organizational data (e.g., financial, service utilization, processes of care, policies) in support of cancer care delivery research studies, and provide site mentoring (as appropriate) in cancer care delivery research.

Definition of Community Site Component: In the context of NCORP Community Site structure, a "component" refers to a hospital, cancer center, physician practice, or other institution where patients/participants are enrolled on a regular and ongoing basis to the menu of NCI-approved clinical trials available to the NCORP Community Site. In addition, one or more of the NCORP Site components are expected to participate in cancer care delivery research. Community Site awardee will be regarded as a "primary component".

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Definition of Community Site Sub-Component: In the context of NCORP Community Site structure, a "sub-component" refers to a practice or organization that contributes to the overall accrual of a component site but is located in a separate geographic location(s), is part of the component's business entity, and is managed by the component.

2.1.2 Annual Accrual Threshold

The sites will need to demonstrate the ability to meet or exceed the required annual 80 new patient/participant accruals evenly distributed over cancer prevention, control and screening/post-treatment surveillance trials and treatment and imaging trials, respectively. The sites will also need to have at least one component site which will provide data collection and study implementation capabilities related to cancer care delivery research, organizational data (e.g., financial, service utilization, processes of care) in support of cancer care delivery research studies, and mentoring for other participating institutions in cancer care delivery research. These capabilities can be provided by a single participating institution or different participating institutions can provide these various capabilities.

2.2 Overall Responsibilities for Community Sites

2.2.1 Scientific Leadership & Contribution to NCORP Activities

- Investigators at NCORP Community Sites can demonstrate scientific leadership for NCORP studies as well as support of and participation in other NCORP activities in a variety of way through their membership in the Research Bases, including but not limited to the following:
- Offering eligible participants in NCORP studies and enrolling sufficient participants to meet accrual targets;
- Participating in research design and protocol development for NCORP studies, including collaborations between Research Bases and other NCI-supported programs and investigators, particularly at their institution;
- Co-authorship on Research Base publications;
- Participating in the Scientific and Administrative Committees of the Research Bases;
- Participating in major meetings of the Research Bases and in other meetings deemed necessary for performance of the activities of NCORP;
- Participating in NCORP activities and initiatives such as the NCI Scientific Steering Committees and associated Task Forces and Working Groups and their activities such as NCI Clinical Trials Planning Meetings or Cancer Care Delivery Planning Meetings;
- Participating as members on the pediatric or adult NCI Central IRB

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- Providing secondary data on patients, providers or organizations from sources such as registries, electronic medical records, other clinical or administrative databases in NCORP studies and providing sufficient data to meet the sample requirements.
- Participating in the Cancer Care Delivery Research Coordination Committee (if applicable)
- Providing data on program characteristics, patterns and organizational policies of care to the affiliated Research Base
- Participate in the activities of the cancer care delivery research Coordinating Committee and adhere to the policies and procedures established by the cancer care delivery research Coordinating Committee related to both scientific and administrative activities of the committee, as applicable.
- Participate in any program evaluation processes that are conducted including interacting with NCI representatives in coordinating the evaluation.

2.2.2 *Young Investigator and Leadership Mentoring/Training*

Each NCORP Community Site should provide a mentorship program or activities to involve young investigators at their institution in cancer prevention, control and screening/post-treatment surveillance clinical trials and cancer care delivery research studies and to help train them eventually to take on senior leadership responsibilities for components of research at the institution.

2.2.3 *Operational Management (Governance/Organization, Institutional Support, Components)*

Governance & Organizational Structure: Each NCORP Community Site is under the leadership of the Site Principal Investigator(s), who coordinate(s) all the scientific and administrative policies at the institution related to NCORP activities as well as coordination with the Research Bases of which the Community Site is a member. The Multiple Principal Investigator (PI) option is encouraged for these awards given the team science approach of the research effort. Information on the Multiple PI Option is available at http://grants.nih.gov/grants/multi_pi/index.htm. If this option is used, the Community Site should designate a "Contact PI" among the multiple PIs. The Principal Investigator (or Contact Principal Investigator under the Multiple PI option) or designee is also responsible for all grant-related activities related to this award and for communication about these activities with the appropriate NCI/DCP staff.

The Community Site is responsible for development and maintenance of a governance and organizational structure to coordinate NCORP activities at the institution. The

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organizational structure of the Community Site should be established with clear and appropriate staff roles and reporting responsibilities, especially with respect to the role and reporting responsibilities of any multiple PIs.

It is anticipated that the Principal Investigator(s) will be integrated into the scientific, clinical and cancer care delivery research activities of each of the Research Bases to which the institution belongs, thereby fostering collaboration between NCORP Network and other investigators at the institution.

NCORP Community Sites will be expected to participate in network-wide cancer care delivery research site data assessment initiatives and integrate these findings to improve their ability to participate in cancer care delivery research studies. Community sites will actively seek participation in cancer care delivery research study concepts that are appropriate to their organization and data collection capabilities.

Component & Sub-Component Network: If the Community Site has component(s) and sub-component(s), the component network must be clearly described (including reference to the distinct CTEP institution code(s) for the component(s) and sub-component(s) that are used for patient enrollment). The Community Site is responsible for complete monitoring and management of the enrollment of patients at the component(s) and sub-component site(s) to NCORP and NCTN clinical trials and cancer care delivery research studies if they are included in the award. The component site(s) participating in cancer care delivery research must be clearly identified. Any post-award changes to components or sub-component sites will need to be approved by NCI per the Organizational Change Guidelines (<http://prevention.cancer.gov/ncorp>).

Institution(s)/site(s) with the following NCTN Network Group membership status may not be included as a component/sub-component site of a NCORP Community Site unless the membership status is relinquished for NCORP Community Site component status:

- NCTN Lead academic participating site (LAP) (academic center and its integrated components)
- Affiliates or sub-affiliates included in a LAP cooperative agreement award
- Network Group Pediatric main member or affiliate sites
- Other Network Group main member, affiliate sites, or sub-affiliate sites.

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2.2.4 NCI Adult and Pediatric Central Institutional Review Board Membership (not applicable to cancer care delivery research)

All U.S. institutions/sites participating in NCORP studies are required to use the NCI Central Institutional Review Board (CIRB) for any NCORP study under the NCI CIRB's purview. The NCI CIRB provides a centralized approach to human subject protection through a process that streamlines local IRB review of adult and pediatric national multi-center cancer treatment trials. The Initiative consists of two central IRBs, one for adult trials and one for pediatric trials. Adult NCORP trials do not currently utilize the CIRB process. See <http://www.ncicirb.org> for information on the requirements for a signatory institution under the NCI CIRBs

2.2.5 Study Operations – Conduct of Studies and Data Management

The Community Sites should have a clearly articulated process for prioritizing which NCORP trials to activate at their institutions. Investigators at Community Sites form the cornerstone of the research programs for NCORP and must perform at a high level through submission of accurate and timely clinical data as well as ancillary materials necessary to support NCORP (e.g., tumor specimens, imaging studies, pathology slides). The Principal Investigator(s) at each Community Site is responsible for the performance of their component sites for which it provides complete management services and for assuring adherence to NCORP, NCI, OHRP, and FDA policies and procedures.

The Community Site should have a process for describing the capabilities of the component(s) designated for participation in cancer care delivery research in the following areas: genetic counseling, multidisciplinary care, care coordination/navigation processes, supportive/palliative care and outreach programs for minority/underserved populations. Community Sites will identify strategies to be used by practitioners and senior management at the institution(s) to support the implementation of cancer care delivery research including providing requested data in support of multi-site studies and participating and allowing staff to participate as subjects of research.

It is the responsibility of the Principal Investigator(s) at the site to ensure that the procedures for data submission for each NCORP protocol are understood by all investigators at the Community Site and its components as well as at any sub-components, and that protocol-specified data are submitted accurately and in a timely manner to the appropriate NCORP Research Base.

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2.2.6 Quality Assurance and Onsite Auditing

Responsibilities for quality assurance of the data (and biospecimens) submitted for NCORP studies as well as auditing include, but are not limited to, the following:

- *Pathology*: Submission of appropriate materials to allow verification of pathologic diagnosis, when relevant.
- *Biospecimens (including integral assays, omics, Pharmacokinetics, Pharmacodynamics)*: Submission of appropriate biospecimens to allow for review/analysis of protocol-specified tests and parameters, when relevant.
- *Radiation therapy*: Submission of appropriate materials to allow review (either concurrent or retrospective) of port films and compliance with protocol-specified radiation doses for individual patients, when relevant.
- *Chemotherapy & Other Systemic Therapies*: Submission of appropriate data to allow determination of protocol compliance with chemotherapy or other systemic therapy dose administration and dosage modification.
- *Surgery*: Submission of appropriate information to allow review of protocol-specified surgical procedures.
- *Diagnostic Imaging*: Submission of appropriate imaging data [images and associated meta-data (clinical or technical) as appropriate] to allow central review of staging, reported responses, and adequacy of imaging when required by a particular protocol or for an audit.
- *Cancer registry data*
- *Electronic or paper-based medical record data*
- *Administrative data (e.g., insurance status, demographic information)*
- *Financial data*
- *Survey or interview data*
- *Onsite Auditing*: Cooperation with Research Bases' data monitoring and onsite auditing programs with appropriate compliance with the onsite auditing program requirements. For clinical trials, see Quality Assurance in Part 1.IV.D.4 for information on the procedures that should be followed in the event that any data irregularities are identified through the audit program or other quality control procedures. For cancer care delivery research, cooperation with Research Bases' data monitoring and onsite auditing programs with appropriate compliance consistent with the Cancer Care Delivery Research Coordination Committee auditing policy.

2.3 Site Clinical Trial Accrual

Community Sites are responsible for accrual to all clinical trial studies conducted across NCORP and its components and subcomponents, and for achieving threshold accruals. Investigators at the Community Sites should be involved in the acquisition of protocol-specified tumor specimens and other biospecimens in addition to all relevant protocol required clinical data. Community Site investigators should ensure that

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biospecimens and/or other data required for ancillary studies are submitted to the appropriate laboratories/tumor banks and Research Base SDMCs.

Community Sites are responsible for assuring that institutional investigators enrolling patients on NCORP studies are NCI registered investigators (i.e., have Form FDA 1572 on file with the NCI). Community Sites also must ensure that the main institution, as well as any components and sub-components, are in compliance with NCI/DCTD/CTEP requirements for storage and accounting for investigational agents, including complying with NCI/DHHS Drug Accountability Records (DAR) procedures as described in the DCTD Investigators' Handbook at: <http://ctep.cancer.gov/handbook/index.html> and are in compliance with FDA requirements for investigational agents.

2.4 Compliance with Federal Regulations for Research

Community Site awardee(s) including the components and sub-components should have policies and procedures for ensuring compliance with federal regulations for the protection of human subjects. These include the following:

- Assuring that all component and sub-component have current, approved Federal wide Assurances (FWAs) on file with OHRP;
- Assuring that each protocol is reviewed by the site IRBs prior to participant entry (or, where applicable, by the NCI CIRB) and that each protocol is reviewed annually by the appropriate IRB as long as the protocol is active;
- Assuring that each participant (or legal representative) gives written informed consent prior to entry on study;
- Where relevant, assuring that all regulatory documents verifying the FWA assurance and initial and annual IRB approval of protocols as well as IRB approval of required amendments are submitted to the Regulatory Support System (RSS) of the NCI Cancer Trials Support Unit (CTSU) for NCORP trials;
- Assuring that all investigators comply with procedures for assuring timely reporting of adverse events, including all expedited reporting of all serious adverse events, per the protocol documents of NCORP studies in which the sites participate.

2.4.1 IRB Review of the Community Site

Institutional Review Board (IRB) review of the Community Site grant is required. The IRB should determine and document that the Community Site has sufficient mechanisms in place to ensure appropriate

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data collection and data management of participants enrolled at the site (and components and sub-components, if applicable) and secondary data collected from the site as well as mechanisms to ensure protection of the confidentiality of participant data, given the nature of the research involved. The IRB will provide appropriate expertise for review of cancer care delivery research studies. Information on this requirement for IRB review can be obtained on the OHRP website at: <http://www.hhs.gov/ohrp/>.

2.4.2 *Inclusion of Women, Minorities, and Children in Clinical Research*

NIH policy requires that women and members of minority groups and ethnic subgroups be included in all NIH-supported research projects involving human subjects at:

http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Compliance with this policy requires appropriate study designs, targets for total protocol accrual with distribution by ethnic/racial categories and by sex/gender, as well as reporting of accrual by ethnic/racial categories and by sex/gender. Since NCORP Research Bases conduct multiple phase 3 clinical trials, the amended NIH Policy on inclusion of women and minorities in research also applies (see NIH Guide Notice on NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>, with a complete copy of the updated Guidelines available at:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

A description of plans to conduct analyses, as appropriate, by sex/gender and/or ethnic/racial groups must be included in protocols and the Research Base SDMC should ensure that it has appropriate procedures in place to address this requirement. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and ethnic/racial differences must be reported in the required Final Progress Report or any future competitive renewal applications.

Community Sites should ensure that it will provide the appropriate demographic data for any NCORP study in which it participates per the protocol so that the Research Base SDMCs can meet these requirements.

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NIH policy requires that children (i.e., individuals under 21 years of age) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them as described at:

<http://grants.nih.gov/grants/funding/children/children.htm>.

2.4.3 Resource Sharing Plans

Generally, Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms if applicable, and GWAS Sharing Plan) are required for all key components of NCORP. However, since it is expected that all data on patients enrolled on NCORP studies by the Community Site will be transmitted to the appropriate Research Base SDMCs, the Resource Sharing Plans of those Research Bases will be applied to the patient data from the Community Sites.

2.4.4 Education on the Protection of Human Subjects

NIH policy requires education on the protection of human subject for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. This policy is available on the NIH website at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

2.4.5 Other Federal Regulations

The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central *upon acceptance for publication*. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication. More information about this policy or the submission process is available on the NIH Public Access Policy website at: <http://publicaccess.nih.gov/>.

Information on other federal regulations (and their associated citations/URLs) that may be applicable to the Community Site's activities is provided in Part 4: Appendices – Section IV.B.

2.5 Conflict of Interest Policy

Community Sites receiving NIH funding from a grant or cooperative agreement must be in compliance with all of the DHSS regulatory requirements for conflict of interest as outlined by NIH grants policy available at: <http://grants.nih.gov/grants/policy/coi>. Community Sites must also comply with the Conflict of Interest Policy of the

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applicable Research Base leading an NCORP study in which the site participates. These policies should ensure that there is no reasonable expectation that any investigator or staff member of the Community Site involved in the design, conduct, or reporting of research will be biased by any conflict of interest (using the definition of investigator provided in the NIH grants policy).

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**3. Specific Awardee Rights & Responsibilities – NCORP
Minority/Underserved Community Sites**

These procedures apply to both cancer prevention, control and screening/post-treatment surveillance clinical trials as well as cancer care delivery research studies except as specifically noted.

3.1 Definition, Eligibility, and Accrual Threshold

Throughout these Terms and Conditions of Award, “NCORP Minority/Underserved Community Site” refers to the organizational structure which is composed of the key personnel (including the scientific and administrative leaders at the Site) responsible for implementing NCORP studies and collaborating on research goals of NCORP with NCORP Research Bases. In addition, throughout these Terms and Conditions of Award, “NCORP Minority/Underserved Community Site,” refers to the main academic institution/site as well as any component and sub-component site(s) included in the award if the Minority/Underserved Community Site provides complete management services for the affiliate site(s) related to enrolling patients on NCORP studies.

3.1.1 Definition of an NCORP Minority/Underserved Community Site

An NCORP Minority/Underserved Community Site is defined as a consortium of community hospitals and/or oncology practices, a public hospital, or academic medical center that has a patient population comprising at least 30% racial/ethnic minorities or rural residents. Minority/Underserved Community Sites will accrue participants to: 1) cancer prevention and control clinical trials designed and conducted by NCORP Research Bases; 2) NCTN-sponsored cancer treatment and imaging trials, as well as quality of life studies embedded within them; and 3) cancer care delivery research studies (where “participants” can be defined as patients, providers, and/or healthcare organizations). NCORP Minority/Underserved Community Sites will also develop and enhance their data collection and study implementation capabilities related to cancer care delivery research, provide organizational data (e.g., financial, service utilization, processes of care) in support of cancer care delivery research studies, and provide site mentoring (as appropriate) in cancer care delivery research. Additionally, Minority/Underserved Community Sites will mentor NCORP Community Sites in disparities-focused research and will identify relevant research questions emanating from their communities. An applicant may be an NCI-Designated Cancer Center if the following apply: at least 30% of its patients are a racial/ethnic minority or rural population; the Center focuses on research and methodologies to analyze outcomes in cancer disparities;

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and the Center can demonstrate experience in community outreach and accrual of minority or rural populations.

Definition of Minority/Underserved Community Site

Component: In the context of NCORP Minority/Underserved Community Site structure, a "component" refers to a hospital, cancer center, physician practice, or other institution where patients/participants are enrolled on a regular and ongoing basis to the menu of NCI-approved clinical trials available to the NCORP Minority/Underserved Community Site. In addition, one or more of the NCORP Site components are expected to participate in cancer care delivery research. Minority/Underserved Community Site awardee will be regarded as a "primary component".

Definition of Minority/Underserved Community Site Sub-

Component: In the context of NCORP Minority/Underserved Community Site structure, a "sub-component" refers to a practice or organization that contributes to the overall accrual of a component site but is located in a separate geographic location(s), is part of the component's business entity, and is managed by the component.

Definition of racial/ethnic minorities or rural populations

- Office and Management Budget (OMB) guidelines will define race/ethnicity (see OMB Statistical Policy Directive No. 15: http://www.whitehouse.gov/omb/fedreg_1997standards). Applications submitted from sites that serve rural areas and wish to be considered for the NCORP Minority/Underserved component should meet the 30 percent requirements for this underserved population using criteria for describing rural populations from sources such as the OMB, U.S. Census Bureau Rural and Urban Taxonomy or the Rural/Urban Commuting-Area Taxonomy. Applicants should address the following to demonstrate that the proposed catchment area has cancer-related provider shortages or cancer service barriers due to lack of proximity to cancer centers or practices (see Health Resources and Services Administration: Defining Rural Populations: http://www.hrsa.gov/ruralhealth/policy/definition_of_rural.html, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449333/>). Please note demographic information can be county-based but must include information about physician-to-population ratios, access to advanced technologies, the environment in which rural physicians practice oncology (e.g., higher overhead, travel from urban or more densely populated towns, high unemployment and poverty among patients,

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cultural barriers) and other features that influence health outcomes among rural populations.

3.1.2 Annual Accrual Threshold

Established Minority/Underserved Sites will be expected to meet or exceed the required annual 80 new patient/participant accruals evenly distributed over cancer prevention, control and screening/post-treatment surveillance trials and treatment and imaging trials, respectively. Under special circumstances, a NCORP Minority/Underserved Community Site (excluding eligible NCI-Designated Cancer Centers) may be allowed to reach the required annual 80 new participant/patient accruals by the end of the project period.

The sites need to have at least one component institution which will provide data collection and study implementation capabilities related to cancer care delivery research, organizational data (e.g., financial, service utilization, processes of care) in support of cancer care delivery research studies, and mentoring for other participating institutions in cancer care delivery research. These capabilities can be provided by a single participating institution or different participating institutions can provide these various capabilities.

3.2 Overall Responsibilities for Minority/Underserved Community Sites

3.2.1 Scientific Leadership & Contribution to NCORP Activities

Investigators at NCORP Minority/Underserved Community Sites can demonstrate scientific leadership for NCORP studies as well as support of and participation in other NCORP activities in a variety of way through their membership in the Research Bases, including but not limited to the following:

- Offering eligible participants participation in NCORP studies and entering sufficient participants to meet accrual targets;
- Participating in research design and protocol development for NCORP studies, including collaborations between Research Bases and other NCI-supported programs and investigators, particularly at their institution;
- Co-authorship on Research Base publications;
- Participating in the Scientific and Administrative Committees of the Research Bases;
- Participating in major meetings of the Research Bases and in other meetings deemed necessary for performance of the activities of NCORP;
- Participating in NCORP activities and initiatives such as the NCI Scientific Steering Committees and associated Task Forces and Working Groups and their activities such as NCI

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- Clinical Trials or cancer care delivery research Planning Meetings;
- Participating as members on the pediatric and adult NCI Central IRB
- Mentoring non-minority and underserved community sites within NCORP regarding community outreach, accrual of minority/underserved populations to studies
- Providing secondary data on patients, providers or organizations from sources such as registries, electronic medical records, other clinical or administrative databases in NCORP studies and providing sufficient data to meet the sample requirements.
- Providing data on program characteristics, patterns and organizational policies of care to the affiliated Research Base
- Participate in the activities of the cancer care delivery research Coordinating Committee and adhere to the policies and procedures established by the cancer care delivery research Coordinating Committee related to both scientific and administrative activities of the committee, as applicable.
- Participate in any program evaluation processes that are conducted including interacting with NCI representatives in coordinating the evaluation.

3.2.2 *Young Investigator and Leadership Mentoring/Training*

Each NCORP Minority/Underserved Community Site should provide a mentorship program or activities to involve young investigators at their institution in cancer prevention and control clinical trials and cancer care delivery research studies and to help train them eventually take on senior leadership responsibilities for components of research at the institution.

3.2.3 *Operational Management (Governance/Organization, Institutional Support, Components)*

Governance & Organizational Structure: Each NCORP Minority/Underserved Community Site is under the leadership of the Site Principal Investigator(s), who coordinate(s) all the scientific and administrative policies at the institution related to NCORP activities as well as coordination with the Research Bases of which the Minority/Underserved Community Site is a member. The Multiple Principal Investigator (PI) option is encouraged for these awards given the team science approach of the research effort. Information on the Multiple PI Option is available at http://grants.nih.gov/grants/multi_pi/index.htm. If this option is used, the Minority/Underserved Community Site should designate a "Contact PI" among the multiple PIs. The Principal Investigator (or Contact Principal Investigator under the Multiple PI option) or designee is also responsible for all grant-related activities related to this award and for

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communication about these activities with the appropriate NCI/DCP staff.

The Minority/Underserved Community Site is responsible for development and maintenance of a governance and organizational structure to coordinate NCORP activities at the institution. The organizational structure of the Minority/Underserved Community Site should be established with clear and appropriate staff roles and reporting responsibilities, especially with respect to the role and reporting responsibilities of any multiple PIs.

It is anticipated that the Principal Investigator(s) will be integrated into the scientific, clinical and cancer care delivery research activities of each of the Research Bases to which the institution belongs, thereby fostering collaboration between NCORP Network and other investigators at the institution. In addition, the Principal Investigator(s) should be well integrated into the scientific and clinical activities of each of the Research Bases to which the institution belongs.

NCORP Minority/Underserved Community sites will be expected to participate in network-wide cancer care delivery research site data assessment initiatives and integrate these findings to improve their ability to participate in cancer care delivery research studies. Minority/Underserved sites will actively seek participation in cancer care delivery research study concepts that are appropriate to their organization and data collection capabilities.

Component & Sub-Component Network: If the Minority/Underserved Community Site has component(s) and sub-component(s), the component network must be clearly described (including reference to the distinct CTEP institution code(s) for the component(s) and sub-component(s) that are used for patient enrollment). The Minority/Underserved Community Site is responsible for complete monitoring and management of the enrollment of patients at the component(s) and sub-component site(s) to NCORP and NCTN clinical trials and cancer care delivery research studies if they are included in the award. The component site(s) participating in cancer care delivery research must be clearly identified. Any post-award changes to components or sub-component sites will need to be approved by NCI per the Organizational Change Guidelines (<http://prevention.cancer.gov/ncorp>).

Institution(s)/site(s) with the following NCTN Network Group membership status may not be included as a component/sub-component site of a NCORP Minority/Underserved Community Site unless the membership status is relinquished for NCORP Minority/Underserved Community Site component status:

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- NCTN Lead academic participating site (LAP) (academic center and its integrated components)
- Affiliates or sub-affiliates included in a LAP cooperative agreement award
- Network Group Pediatric main member or affiliate sites
- Other Network Group main member, affiliate sites, or sub-affiliate sites.

3.2.4 NCI Adult and Pediatric Central Institutional Review Board Membership

All U.S. institutions/sites participating in NCORP studies are required to use the NCI Central Institutional Review Board (CIRB) for any NCORP study under the NCI CIRB's purview. The NCI CIRB provides a centralized approach to human subject protection through a process that streamlines local IRB review of adult and pediatric national multi-center cancer treatment trials. The Initiative consists of two central IRBs, one for adult trials and one for pediatric trials. Adult NCORP trials do not currently utilize the CIRB process. See <http://www.ncicirb.org> for information on the requirements for a signatory institution under the NCI CIRBs

3.2.5 Study Operations and Data Management

The Minority/Underserved Community Sites should have a clearly articulated process for prioritizing which NCORP trials to activate at their institutions. Investigators at Minority/Underserved Community Sites form the cornerstone of the research programs for NCORP and must perform at a high level through submission of accurate and timely clinical data as well as ancillary materials necessary to support NCORP (e.g., tumor specimens, imaging studies, pathology slides). The Principal Investigator(s) at each Minority/Underserved Community Site is responsible for the performance of the academic center and its components as well as of any sub-components for which it provides complete management services and for assuring adherence to NCORP, NCI, OHRP, and FDA policies and procedures.

The Minority/Underserved Community Site should have a process for describing the capabilities of the component(s) designated for participation in cancer care delivery research in the following areas: genetic counseling, multidisciplinary care, care coordination/navigation processes, supportive/palliative care and outreach programs for minority/underserved populations. Minority/Underserved Community Sites will identify strategies to be used by practitioners and senior management at the institution(s) to support the implementation of cancer care delivery research including providing requested data in support of multi-site studies and

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participating and allowing staff to participate as subjects of research.

It is the responsibility of the Principal Investigator(s) at the site to ensure that the procedures for data submission for each NCORP protocol are understood by all investigators at the academic center and its components as well as at any sub-components, and that protocol-specified data are submitted accurately and in a timely manner to the appropriate NCORP Research Base.

3.2.6 *Quality Assurance and Onsite Auditing*

Responsibilities for quality assurance of the data submitted for NCORP studies as well as auditing include, but are not limited to, the following:

- *Pathology*: Submission of appropriate materials to allow verification of pathologic diagnosis, when relevant.
- *Biospecimens (including integral assays, -omics, Pharmacokinetics, Pharmacodynamics)*: Submission of appropriate biospecimens to allow for review/analysis of protocol-specified tests and parameters, when relevant.
- *Radiation therapy*: Submission of appropriate materials to allow review (either concurrent or retrospective) of port films and compliance with protocol-specified radiation doses for individual patients.
- *Chemotherapy & Other Systemic Therapies*: Submission of appropriate data to allow determination of protocol compliance with chemotherapy or other systemic therapy dose administration and dosage modification.
- *Surgery*: Submission of appropriate information to allow review of protocol-specified surgical procedures.
- *Diagnostic Imaging*: Submission of appropriate imaging data [images and associated meta-data (clinical or technical) as appropriate] to allow central review of staging, reported responses, and adequacy of imaging when required by a particular protocol or for an audit.
- *Cancer registry data*
- *Electronic or paper-based medical record data*
- *Administrative data (e.g., insurance status, demographic information)*
- *Financial data*
- *Survey or interview data*
- *Onsite Auditing*: Cooperation with Research Bases' data monitoring and onsite auditing programs with appropriate compliance with the onsite auditing program requirements. For cancer care delivery studies, cooperation with Research Bases' data monitoring and onsite auditing programs with appropriate compliance consistent with the Cancer Care Delivery Research Coordination Committee auditing policy. See Quality Assurance in Part 1.IV.D.4 for information on the procedures that should be followed in the event that

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any data irregularities are identified through the audit program or other quality control procedures.

3.3 Site Clinical Trial Accrual

Minority/Underserved Community Sites are responsible for accrual to clinical trials conducted across NCORP from its components and its subcomponents, and for achieving threshold accruals. Investigators at the Minority/Underserved Community Sites should be involved in the acquisition of protocol-specified tumor specimens and other biospecimens in addition to all relevant protocol required clinical data. Minority/Underserved Community Site investigators should ensure that biospecimens and/or other data required for ancillary studies are submitted to the appropriate laboratories/tumor banks and Research Base SDMCs.

Minority/Underserved Community Sites are responsible for assuring that institutional investigators enrolling patients on NCORP clinical trials are NCI registered investigators (i.e., have Form FDA 1572 on file with the NCI). Minority/Underserved Community Sites also must ensure that the main institution, as well as any components and sub-components, are in compliance with NCI/DCTD/CTEP requirements for storage and accounting for investigational agents, including complying with NCI/DHHS Drug Accountability Records (DAR) procedures as described in the DCTD Investigators' Handbook at: <http://ctep.cancer.gov/handbook/index.html> and are in compliance with FDA requirements for investigational agents.

3.4 Compliance with Federal Regulations for Research

Minority/Underserved Community Site awardee(s) should have policies and procedures for ensuring compliance by the main academic center and its components (and any sub-components completely managed by the main academic institution/site) with the policies and procedures for meeting federal regulations for the protection of human subjects. These include the following:

- Assuring that all sites have current, approved Federal-wide Assurances (FWAs) on file with OHRP;
- Assuring that each protocol is reviewed by the site IRBs prior to participant entry (or, where applicable, by the NCI CIRB) and that each protocol is reviewed annually by the appropriate IRB as long as the protocol is active;
- Assuring that each participant (or legal representative) gives written informed consent prior to entry on study;
- Where relevant, assuring that all regulatory documents verifying the FWA assurance and initial and annual IRB approval of protocols as well as IRB approval of required amendments are submitted to the Regulatory Support System

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(RSS) of the NCI Cancer Trials Support Unit (CTSU) for NCORP trials;

- Assuring that all investigators comply with procedures for assuring timely reporting of adverse events, including all expedited reporting of all serious adverse events, per the protocol documents of NCORP studies in which the sites participate.

3.4.1 IRB Review of the Minority/Underserved Site

Institutional Review Board (IRB) review of the Minority/Underserved Community Site grant is required. The IRB should determine and document that the Minority/Underserved Community Site has sufficient mechanisms in place to ensure appropriate data collection and data management of participants enrolled at the site (and affiliates, if applicable) and secondary data collected from the site as well as mechanisms to ensure protection of the confidentiality of patient data, given the nature of the research involved. The IRB will provide appropriate expertise for review of cancer care delivery research studies. Information on this requirement for IRB review can be obtained on the OHRP website at: <http://www.hhs.gov/ohrp/>.

3.4.2 Inclusion of Women, Minorities, and Children in Clinical Research

NIH policy requires that women and members of minority groups and ethnic subgroups be included in all NIH-supported research projects involving human subjects at: http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Compliance with this policy requires appropriate study designs, targets for total protocol accrual with distribution by ethnic/racial categories and by sex/gender, as well as reporting of accrual by ethnic/racial categories and by sex/gender. Since NCORP Research Bases conduct multiple phase 3 clinical trials, the amended NIH Policy on inclusion of women and minorities in research also applies (see NIH Guide Notice on NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>, with a complete copy of the updated Guidelines available at:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. A description of plans to conduct analyses, as appropriate, by sex/gender and/or ethnic/racial groups must be included in clinical trial protocols and the Research Base SDMC should ensure that it has appropriate procedures in place to address this requirement. Cumulative subject accrual and progress in conducting subset analyses

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must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and ethnic/racial differences must be reported in the required Final Progress Report or any future competitive renewal applications. Minority/Underserved Community Sites should ensure that it will provide the appropriate demographic data for any NCORP study in which it participates per the protocol so that the Research Base SDMCs can meet these requirements.

NIH policy requires that children (i.e., individuals under 21 years of age) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them as described at: <http://grants.nih.gov/grants/funding/children/children.htm>.

3.4.3 Resource Sharing Plans

Generally, Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms if applicable, and GWAS Sharing Plan) are required for all key components of NCORP. However, since it is expected that all data on patients enrolled on NCORP studies by the Minority/Underserved Community Site will be transmitted to the appropriate Research Base SDMCs, the Resource Sharing Plans of those Research Bases will be applied to the patient data from the Minority/Underserved Community Sites.

3.4.4 Education on the Protection of Human Subjects

NIH policy requires education on the protection of human subject for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. This policy is available on the NIH website at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

3.4.5 Other Federal Regulations

The [NIH Public Access Policy](#) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive [PubMed Central upon acceptance for publication](#). To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication. More information about this policy or the submission process is available on the NIH Public Access Policy website at: <http://publicaccess.nih.gov/>.

Information on other federal regulations (and their associated citations/URLs) that may be applicable to the Minority/Underserved Community Site's activities is provided in Part 4: Appendices – Section IV.B.

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3.5 Conflict of Interest Policy

Minority/Underserved Community Sites receiving NIH funding from a grant or cooperative agreement must be in compliance with all of the DHSS regulatory requirements for conflict of interest as outlined by NIH grants policy available at:

<http://grants.nih.gov/grants/policy/coi>. Minority/Underserved Community Sites must also comply with the Conflict of Interest Policy of the applicable Research Base leading an NCORP study in which the site participates. These policies should ensure that there is no reasonable expectation that any investigator or staff member of the Minority/Underserved Community Site involved in the design, conduct, or reporting of research will be biased by any conflict of interest (using the definition of investigator provided in the NIH grants policy).

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C. NCI/DCP and DCCPS Staff Responsibilities

The role of the NCI Division of Cancer Prevention (DCP)/Community Oncology Prevention Trials Research Group (COPTRG) staff, and Division of Cancer Control and Population Sciences (DCCPS)/Outcomes and Research Branch (ORB) staff as described throughout these Terms and Conditions of Award, is to assist, facilitate, and ensure optimal coordination of NCORP activities, which are integrated into a larger National Clinical Trials Network (NCTN) (details about the NCTN can be found at http://ctep.cancer.gov/investigatorResources/docs/NCTN_Program_Guidelines.pdf). DCP/COPTRG staff has very specific and well-defined responsibilities for the oversight and review of NCORP Research Base cancer prevention, control and screening/post-treatment surveillance trials. DCP/COPTRG and DCCPS/ORB staff is also responsible for oversight and review of activities of NCORP Community/Minority-Underserved Community Sites. Both DCP/COPTRG and (DCCPS)/ORB staff have specific responsibilities for the oversight and review of NCORP Research Base cancer care delivery research studies. The responsibilities of DCP/COPTRG and DCCPS/ORB staff are described below.

1. NCI Responsibilities Related to NCORP Research Bases

1.1 Coordination of National Priorities

NCI/DCP staff is responsible for maintaining a clear set of national priorities for cancer prevention, control and screening/post-treatment surveillance research, based upon substantial consultation with experts in the field. Additionally, NCI/DCCPS staff will maintain a clear set of national priorities for cancer care delivery research, based upon substantial consultation with experts in the field. In selected topic areas, particularly when spontaneous planning does not occur within the Research Bases, DCP and DCCPS staff (with support from the Coordinating Center for Clinical Trials [CCCT]) will help in coordinating the organization of Study Planning Meetings under the auspices of the NCI Scientific Steering Committees. In addition, DCP and DCCPS staff may support ad hoc scientific meetings to help achieve consensus on critical research problems. These Study Planning meetings and ad hoc meetings will be composed of investigators with established expertise in the particular field of interest and will consist primarily of extramural scientists and members of the SSCs. Priorities will be based upon the state of the science, NCORP Research Base resources, and availability of funds. NCI staff will be responsible for prompt dissemination of the recommendations from these meetings, particularly regarding statements of research priorities from Study Planning meetings, and the Research Bases will be encouraged to address these priorities.

1.2 Scientific Resource for NCORP Research

The NCORP Director and Chief, COPTRG, DCP, the NCORP Associate Director and Chief, Outcomes Research Branch, Applied

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Research Program, DCCPS, and DCP and DCCPS Program Directors all serve as resources available to NCORP Research Bases for specific scientific information with respect to cancer prevention, control, screening/post-treatment surveillance and cancer care delivery studies and their design. The NCI/DCP staff also work closely with the NCI/DCTD staff to ensure there is a high level of integration of complementary research efforts on specific trials across the larger NCTN.

The DCP and DCCPS staff listed above will assist NCORP Research Bases as appropriate, in developing information concerning the scientific basis for specific trials or alternative study designs, operational and regulatory issues, and will also be responsible for advising the Research Bases of the nature and results of relevant trials and other studies being carried out nationally or internationally. Where applicable, DCP/COPTRG staff will also provide updated information to the Research Bases on the efficacy, toxicity, and availability of all Investigational New Drugs (IND) supplied by NCI to the Research Bases. In addition, DCP staff advises the Research Bases of potential agents/interventions that will be relevant to new avenues of cancer prevention, control and screening/post-treatment surveillance. In addition DCCPS/ORB will provide updated information to compliment research initiatives and projects as part of other NCI research cancer care delivery projects that may be relevant to NCORP research priorities and concept development.

1.3 Scientific and Administrative Program Directors Activities

The NCORP Director is the NIH/NCI Program Official responsible for the routine scientific and programmatic stewardship of all the awards for NCORP and will be named in the award notice. The NCORP Associate Director will be named in the award notice for cancer care delivery research components of NCORP as he/she has major responsibilities in assisting the NCORP Director for the scientific and programmatic stewardship of the awards.

Each NCORP Research Base will also have a staff physician, nurse, and/or other professional staff member from DCP/COPTRG assigned to them who acts as liaison for scientific and administrative matters related to clinical trials and clinical research studies. The DCP/COPTRG Program Director serves as the primary contact for scientific inquiries, including information concerning the content of specific protocols or Concept reviews, and feedback on general scientific direction of NCORP Research Base. On occasion, the NCORP Director may also serve as Program Director.

Each NCORP Research Base also will have clinical, health services and behavioral research expertise from DCCPS to act as liaisons for scientific and administrative matters related to cancer care delivery research studies. The DCCPS/ORB Program Director serves as the primary contact for scientific inquiries, including

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information concerning the content of specific protocols or Concept reviews, and feedback on general scientific direction of NCORP Research Base. On occasion, the Associate Director may also serve as Program Director.

The Program Director monitors the Research Base's progress, attends their meetings, and is responsible for understanding the Research Base's repertoire of studies and scientific activities, including areas of special interest, expertise, and unique resources.

1.4 Attendance at Meetings of NCORP Research Base

NCI/DCP and NCI/DCCPS Program Directors and other NCI staff, as designated by the NCORP Director and/or Associate Director, will attend the regular Research Base meetings and core scientific Research Base meetings, as appropriate. As part of their responsibilities, Program Directors, when available, will attend other Research Base scientific meetings and may also attend Research Base Executive Committee meetings, and the Cancer Care Delivery Research Coordination Committee.

1.5 Concept, Protocol, and Amendment Development, Review, and Approval: Cancer Prevention and Control and Cancer Care Delivery Research Studies

NCI/DCP and DCCPS staff will be closely involved in the development of NCORP studies. NCI/DCP and DCCPS staff will communicate with NCORP Research Bases during all stages of study development. All concepts for cancer prevention, control, and care delivery studies must be submitted to the NCI DCP Protocol Information Office (PIO) at:
<http://prevention.cancer.gov/clinicaltrials/management.pio>.

The general process for receiving approval of proposed studies is as follows:

- A concept is submitted for review to the DCP Protocol Information Office (PIO);
- If the concept is approved (see 3.1), a protocol document with an informed consent document is submitted for review to the DCP PIO (see 3.2).

NCI/DCP and DCCPS staff is responsible for conducting the review process for concepts, protocols, and amendments as described herein. Review from NCI's SSCs is provided only during the concept review process. Protocol reviews occur within 4-6 weeks after receipt of protocol. This allows time to schedule reviewers and also gives reviewers adequate time to review the protocol.

1.5.1 Concept Review

NCI program staff reviews each submitted concept to determine that the proposed research is relevant to cancer

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prevention, control, and/or care delivery and that the concept includes all required components. NCI program staff will return to Research Bases concepts that do not fulfill these criteria together with a letter that explains the reasons for not accepting the concept for review.

1.5.1a Scientific Steering Committees (SSCs)

The NCI SSCs most relevant to the work of NCORP are the Symptom Management and Quality of Life Scientific Steering Committee and the Clinical Imaging Scientific Steering Committee. The Symptom Management and Quality of Life Steering Committee evaluates symptom management intervention clinical trial concepts conducted through NCORP for scientific merit. The Clinical Imaging Steering Committee evaluates large primary advanced imaging studies for scientific merit.

NCORP concept review by a SSC is based on the area of study:

- Concepts related to cancer symptom management or quality of life are evaluated by the NCI Symptom Management and Quality of Life Scientific Steering Committee.
- Concepts related to cancer screening and prevention are evaluated by the Division of Cancer Prevention (DCP) Concept Review Committee (CRC), with ad hoc extramural scientific reviewers, as needed.
- Concepts related to cancer surveillance are evaluated and prioritized by the Clinical Imaging Steering Committee or by the Division of Cancer Prevention (DCP) Concept Review Committee (CRC), with ad hoc extramural scientific reviewers, depending on the modality under investigation.
- Concepts related to cancer care delivery are evaluated by the DCCPS CRC, with assistance from external reviewers with ad hoc extramural scientific reviewers, as needed.
- Biomarker, Imaging and Quality of Life Studies Funding Program (BIQSFP) applications that are related to cancer prevention and control or cancer care delivery are evaluated by the appropriate NCI SSC (or by DCP's CRC or

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DCCPS's CRC with ad hoc extramural scientific reviewers).

- Concepts related to treatment and imaging clinical trials are reviewed by NCI disease-oriented SSCs health-related quality of life/patient-reported outcomes embedded in treatment trials. DCP provides the expertise during the review of parent trials.

This triage process for evaluation and prioritization of proposed concepts is subject to change (i.e., NCI may choose in the future to institute specific SSCs for cancer screening, prevention, and control studies. In addition, a Cancer Care Delivery Research SSC will be formed.

Prior to presentation at a SSC, the DCP CRC or DCCPS CRC evaluates all NCORP concepts for the scientific rationale, programmatic relevance; potential impact on cancer prevention, control and care delivery; priority; design; statistical requirements; plans for conducting the proposed study; the feasibility and appropriateness of the research for use by NCORP Community Sites or in a community setting; the existence and nature of concurrent clinical trials/studies in the area of research, including research in other NCI-funded programs that may compete with or complement the proposed study; and, where applicable, the availability of investigational agents.

The DCP CRC or DCCPS CRC drafts a review letter of the concept which considers the following evaluative criteria: strength of the scientific rationale supporting the study; clinical importance of the question being proposed; avoidance of undesirable duplication with ongoing studies; appropriateness and feasibility of study design; appropriateness of participant selection, evaluation, and when applicable, assessment of toxicity, measurement of response to intervention, and plans for follow-up; participant safety; compliance with NIH and federal regulatory requirements; satisfactory projected accrual rate and follow-up period; adequacy of data management. This review is provided to the SSC for consideration during its assessment of the NCORP concept.

Several NCI/DCP staff are full members of specific SSCs relevant to cancer prevention, control. DCCPS staff will be appointed, as appropriate, to serve on specific SSCs relevant to cancer care delivery research. Designated NCI staff are voting members of the SSCs. Approval

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NCI staff has special responsibilities on these NCI SSCs, including developing meeting agendas with the SSCs co-Chairs, preparing the Consensus Evaluations for concepts evaluated by the committees, and working with the SSC Co-Chairs on the scientific direction of the committee.

Any change in the policies and procedures of the NCI SSCs related to composition of committee membership, conflict of interest, and evaluation/prioritization procedures for NCORP studies requires review and approval by the NCORP Director, NCI/DCP, and the Associate Director, NCI/DCCPS to ensure that procedures are consistent with the intent of NCORP and the Terms and Conditions of Award under the Cooperative Agreements for all key components of NCORP.

1.5.1b Review Outcome

The appropriate NCI SSC (or the DCP/DCCPS CRCs, as described above) discusses the submitted concept at a meeting with assigned reviewers and committee members and makes a decision on the concept from one of the 3 options provided below:

- ***Approved as written or with recommendations*** – The SSC,DCP CRC OR DCCPS CRC approves the concept and does not need to evaluate a revised concept. The Research Base can begin to develop the protocol. The concept review letter can include important comments and/or recommendations for items to be included in the protocol; NCORP Research Base must respond to these comments and recommendations in a cover letter accompanying the protocol.
- ***Revise and Resubmit*** – The SSC,DCP CRC OR DCCPS CRC has determined that the concept requires additional information or has design issues that can be addressed within three months and requires the investigators to address the itemized concerns in a cover letter that accompanies a revised concept. This option can also indicate that the SSC or DCP CRC has determined that the concept as written lacks adequate scientific justification or is not feasible to conduct, but that relatively modest changes to the study design might address these concerns. The deadline for resubmission will be

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included in the Consensus Evaluation letter sent to the Research Base and the Study PI(s).

- ***Disapproved*** – In the judgment of the SSC, DCP CRC OR DCCPS CRC, the concept as written is not feasible and/or lacks adequate scientific merit, and the changes necessary to address these concerns would result in a study that is substantially different from the study proposed. Disapproval can also indicate that preclinical/early phase studies do not exist to support conduct of the proposed phase II or III trial. Research Bases cannot resubmit disapproved concepts, even with revisions. However, concepts for study of the same subject area with a substantially different study design and/or with inclusion of results from necessary preclinical/early phase studies will be considered new concepts for review.

All concepts that are prioritized for further development by SSCs must undergo expedited review by DCP or DCCPS before final approval is given in order to ensure significant safety, feasibility, and regulatory issues are adequately addressed, including ensuring that there are adequate resources available to NCORP to conduct the study, and to prevent duplication.

All approved DCP Concepts for a phase 3 or phase 2/3 trial is submitted to FDA for comment and all approved DCP Concepts with an investigational device/biomarker for the particular clinical setting may be submitted to FDA for comment even if the study is not identified as being specifically designed for a licensing indication for an agent or device.

1.5.1c Correlative science studies

Correlative science studies embedded in NCORP clinical trials/studies at the time of initial concept submission should be appropriately designed as integral and/or integrated studies with robust statistical designs and analysis plans that address specific and important scientific hypotheses. Exploratory studies and those without a specific hypothesis and robust statistical analysis plan will not be approved. Although optional collection of biospecimens without an approved research plan may be approved for a trial, use of the specimen must be approved by DCP and must be based on studies with specific hypotheses and

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statistical analysis plans (i.e., biospecimens cannot be “reserved” for future unspecified research without a subsequent study proposal being reviewed and approved).

1.5.2 Protocol Review

DCP/COPTRG will assist the Research Bases in clinical trial design to develop a mutually acceptable protocol compatible with the research interests, capabilities, and needs of the Research Base, its affiliates, and NCI.

DCP conducts the only review of clinical trial protocols. All input from NCI’s SSCs occurs during the concept review process. Protocol reviews occur within 4-6 weeks after receipt of protocol. This allows time to schedule reviewers and also gives reviewers adequate time to review the protocol. DCCPS/ORB will assist the Research Bases in study design to develop a mutually acceptable protocol compatible with the research interests, capabilities, and needs of the Research Base, its affiliates, and NCI.

DCCPS will conduct the only review of cancer care delivery protocols. All input from NCI’s SSCs occurs during the concept review process. Protocol reviews occur within 4-6 weeks after receipt of protocol. This allows time to schedule reviewers and also gives reviewers adequate time to review the protocol.

1.5.2a Review Group

The standing Cancer Prevention and Control Protocol Review Committee will be augmented as needed by invited reviewers inside and/or outside the NCI. The reviewers for the protocol often include the same reviewers as those for the concept, but this is not always the case. The chair of the Cancer Prevention and Control Protocol Review Committee conducts the reviews and is the principal contact with investigators regarding protocols under review.

The standing DCCPS Cancer Care Delivery Protocol Review Committee will be augmented as needed by invited reviewers inside and/or outside the NCI. The reviewers for the protocol often include the same reviewers as those for the concept, but this is not always the case. The chair of the DCCPS Cancer Care Delivery Protocol Review Committee conducts the reviews and is the principal contact with investigators regarding protocols under review.

1.5.2b Review Purpose

The protocol review will focus on the inclusion in the protocol of all information and procedures necessary

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for conducting a successful study. Specific attention is paid to responses to concerns of the SSC and/or DCP/DCCPS conveyed to the Research Base at the time of concept approval. Since the rationale for the study and the broad study design have already received, these are not generally the focus of a protocol review. However, if the protocol differs from the concept in significant ways (e.g. change in endpoint, change in participant eligibility criteria), the Protocol Review Committee will review all aspects of the protocol to determine that the study has scientific validity and is feasible to conduct in NCORP network.

If the protocol is for a study that will receive government or non-government funding other than that in NCORP grant and has received approval from a peer review panel, the Division of Cancer Prevention considers the earlier peer review as a concept approval. Protocol review for these studies is similar to reviews for other NCORP protocols, but the Protocol Review Committee will also evaluate feasibility and appropriateness of the study for use in the NCORP network.

1.5.2c Review Outcome

DCP will send all correspondence by mail and/or email regarding protocol reviews to the: 1) Principal Investigator of the Research Base, 2) Study Chair, and 3) one other person designated by each Research Base to receive copies of correspondence related to all concepts and protocols under review at DCP. DCP sends results of protocol reviews within four weeks of the review meeting.

Protocol review letters can take one of four forms:

1. Protocol Approved

The PRC has determined that the protocol is ready for use in the NCORP network.

The approval letter includes the credit assignment for the protocol, when applicable.

2. Protocol Approval on Hold

The PRC has determined that the protocol is suitable for conducting a study in the NCORP network and that no further changes are required to the protocol at the present time. However,

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further reviews and/or approvals by other components of NCI are required before DCP will issue a final approval. Examples include need for approval by a Central IRB or approval of plan for drug distribution for agents that will be distributed by NCI.

3. Revise and Resubmit

The Committee has identified potentially remediable problems that the investigators should review and comment on. These problems usually require revisions to the protocol. DCP/DCCPS will send a review letter that states this decision and includes a list of all issues that require response by investigators.

Investigator should respond to all the Committee's comments, change the protocol where necessary, and resubmit to the DCP Protocol Information Office as a revised protocol for further review. The review letter includes a date by which the revised protocol is due to DCP.

4. Protocol Disapproved

NOTE: Protocol disapproval is not common because approval of the concept indicated NCI's support for the proposed research. However, the Cancer Prevention and Control Protocol Review Committee and/or the DCCPS Cancer Care Delivery Research Protocol Review Committee reserves the right to disapprove a protocol, particularly when the protocol differs significantly from the approved concept.

If DCP disapproves a protocol, it will send a review letter that states this decision and provides reasons for the decision.

All pediatric study protocols (except phase 1 study protocols - although these may be included in the future) require approval by the NCI Pediatric CIRB **prior** to final approval of the study protocol document by NCI/DCP.

1.5.3 Amendment Review

Any change to the protocol document subsequent to its approval by DCP must be submitted to DCP's Protocol and Information Office (PIO) in writing for review and approval by DCP prior to implementation of the change, with the exception

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of administrative updates. Additional information on the procedures for protocol amendment can be found in Section **1.3.2.3** of these Guidelines and in the Investigator's Handbook.

The Cancer Prevention and Control Protocol Review Committee and for cancer care delivery research, the DCCPS Cancer Care Delivery Research Protocol Review Committee, will review all amendments within 2 weeks of receipt in DCP PIO. Research Bases will receive a response within 2 weeks after review.

The PRC will determine one of two outcomes for each submitted amendment: **approval** or **disapproval**. All changes requested require approval for the amendment to receive approval.

It will convey the results of the review to the Research Base chair and the Study Chair in a response letter within 2 weeks of review. The response letter will include reasons for disapproval for all disapproved amendments.

The Research Base can revise disapproved amendments in response to PRC's comments and resubmit as new amendments.

1.6 Data and Safety Monitoring Boards (Data Monitoring Committees)

The NCORP Director will designate Program Directors to serve as cancer prevention and control liaisons on Data and Safety Monitoring Boards (DSMBs), also known as Data Monitoring Committees (DMCs), for NCORP phase 3 trials as well as phase 2/3 and any other phase 2 trials monitored by the DSMB/DMC. One or more DCP/COPTRG staff will serve as non-voting members at each Research Base DSMB/DMC meeting. NCI/DCP Program Directors will review Research Base mechanisms for interim monitoring of results, will monitor clinical trial progress, and will assess Research Base compliance with NCI-established policies on Data and Safety Monitoring Plans for Phase I and II trials and Data and Safety Monitoring Committees for Phase III trials. NCORP Research Base DSMBs/DMCs must comply with all NCI membership and operational policies as established through the NCTN guidelines (available at: http://ctep.cancer.gov/investigatorResources/docs/NCTN_Program_Guidelines.pdf).

Because NCI/DCP staff serve as non-voting members of the Research Base DSMBs/DMCs, to ensure compliance with NIH/NCI policies and protocol requirements, NCI/DCP staff members recuse themselves from NCI/DCP review of substantive protocol amendments (e.g., amendments for increases in sample size or significant changes in trial design) for any study that is also under review by a DSMB/DMC of which they are members, if confidential outcome data on that study have been previously presented to the DSMB/DMC. When this

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situation arises, the amendment is reviewed by NCI/DCP staff members who are not members of that DSMB/DMC.

1.7 Coordination of Resources to Enhance Accrual/Completion of NCORP Studies

DCP/COPTRG and DCCPS/ORB staff will take an active role in promoting the timely completion of studies, for example, by encouraging and facilitating collaboration among the Research Bases and collaborations with other NCI-supported programs and investigators when appropriate or by assisting in the mobilization of other available and required resources to enhance accrual to and/or completion of NCORP trials and other studies.

1.8 Study/Trial Closure

NCI/DCP may request that a phase 1 or phase 2 study be closed to accrual for reasons including the following: (1) insufficient accrual rate; (2) poor protocol performance; (3) protection of patient safety; (4) study results are already conclusive; (5) emergence of new information that diminishes the scientific importance of the study question; and (6) unavailability of study agent. NCI will not provide investigational agents or permit expenditures of NCI funds for a phase 1 or phase 2 study after requesting closure (except for patients on treatment and follow-up).

NCI/DCCPS may request that a cancer care delivery research study be closed to accrual for reasons including but not limited to the following: (1) insufficient accrual of study participants; (2) poor protocol performance; (3) protection of participants; (4) study results are already conclusive; (5) emergence of new information that diminishes the scientific importance of the study question; and (6) poor quality of critical data necessary to complete the study.

1.8.1 Early Stopping Rules for Slowly-Accruing Studies (Phase 2 and Phase 3)

The following early stopping guidelines for slowly-accruing phase 2 and 3 studies conducted under NCORP are stated in terms of the percentage of projected accrual during specified quarters after activation. For example, Quarter 5-6 accrual signifies the number of patients enrolled on study during Quarters 5 and 6 after activation, divided by the number of patients that were projected to be enrolled during that time period based on the accrual rate specified in the protocol.

1.8.1a Guidelines for Early Stopping for Clinical Trials

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If Quarter 5-6 accrual is $\leq 20\%$ of projected, the Research Base is strongly encouraged to stop the study. In extraordinary circumstances the DCP Program Director for the Research Base can agree to accept for review an amendment to change the accrual goals or to change the protocol with the intent of increasing accrual.

If Quarter 5-6 accrual is $< 50\%$ and $> 20\%$ of projected, then the study team has 6 months to improve accrual.

If Quarter 8 accrual is $< 50\%$ of projected, then the research base should submit an amendment to DCP PIO to reflect actual accrual. The investigators should consider including scientifically valid changes to the amendment intended to increase accrual. The implications of the new accrual rate on study relevance and feasibility should be discussed in the proposed amendment.

1.8.1b Implementation for Clinical Trials

Protocols submitted to DCP for review must include an estimate of planned accrual rate. The DCP Cancer Prevention and Control Protocol Review Committee will review this estimate with regard to how realistic the estimate is and the relevance of study results at the end of the planned accrual time. As soon as the Quarter 5 and 6 accrual figures become available, the Research Base Statistics and Data Management Center will provide to the Research Base chair and the DCP PIO average accrual for Quarters 5 and 6, projected accrual for Quarters 5 and 6 from the protocol, total accrual Quarters 1 to 6, and projected accrual for Quarters 1 to 6 from the protocol. The Research Base chair will either close the trial or notify the investigators and NCI that they have another 6 months in which to improve accrual according to the guidelines described above.

Amendments that include changes related to low accrual as determined by the accrual reports from Quarters 5 and 6 or Quarter 8 (see previous paragraphs) must identify these guidelines as the basis of the amendment and should include background information

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describing the actual accrual compared to the projected accrual, potential reasons for the slow accrual, explanations for expecting changes to increase accrual (if applicable), and an explanation for the relevance of the study given new accrual goals and other proposed changes to the protocol (e.g. a change in eligibility criteria). The DCP Cancer Prevention and Control Protocol Review Committee will consider this information when reviewing the amendment.

For studies that are closed or amended, the Research Base will notify the Group Data and Safety Monitoring Board (DSMB) of the closure or amendment at their next regularly scheduled meeting. Research Base chairs may consult with their DSMB regarding the decision for early closure, if desired. In the unusual circumstance that the Research Base Chair believes that the guidelines are inappropriate for a given study, he or she will initiate a discussion with the responsible NCI Program Director to reach a joint decision concerning what course to take.

1.9 Quality Assurance and Onsite Auditing

1.9a Clinical Trials

NCI/DCP Program Directors will review quality control and monitoring procedures of the Research Bases including the on-site auditing program, and may attend on-site audits conducted by the Research Base or its NCI designee.

The Clinical Trials Monitoring Branch (CTMB) is responsible for establishing guidance for the conduct of quality assurance audits. CTMB provides oversight and monitors compliance of the Network Groups, NCORP Research Bases, and CTSU with the NCI's monitoring guidelines. Compliance with applicable federal regulations is also monitored by CTMB.

In addition, CTMB staff serves as an educational resource to the cancer research community on issues related to monitoring and regulatory requirements for the conduct of clinical trials. CTMB staff review audit reports and findings and assess the adequacy and acceptability of any corrective actions. To assure

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consistency in the conduct of onsite audits, CTMB staff or its designee(s) may attend certain onsite audits.

The CTMB has developed the CTMB Audit Information System which permits the on-line submission by the Research Bases of all data related to quality assurance onsite. This includes the submission of audit schedules, acknowledgment of receipt of preliminary reports, transmission of final audit reports, and tracking of follow-up responses to audit findings. The system allows restricted access to the stored data and keeps a record of any data changes. The CTMB Audit Information System can be accessed only after providing a username and password. A major component of the CTMB Audit Information System is a module that maintains a roster of all its member sites in each Research Base. This roster information is used for determining compliance with monitoring requirements.

Each NCORP Research Base is responsible for ensuring that all member sites have routine audits in accordance with the NCI-CTMB Guidelines for Monitoring of Clinical Trials for Cooperative Groups, NCORP Research Bases, and the Cancer Trials Support Unit (CTSU) at: http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_coop_ccop_ctsu.htm and that the results of audits are reported to the NCI in accordance with the guidelines. In the event that the NCI/CTMB determines that a Research Base member fails to comply with these guidelines, the CTMB may, in consultation with the Research Base, suspend the member institution/site immediately from participating in any NCORP trials led by the Research Base or all NCORP trials regardless of the Research Base leading the study. The suspension will remain in effect until the Research Base conducts the required audit and the audit report or remedial action is accepted by the Research Base and the NCI.

Each NCORP Research Base will be responsible for notifying any affected member site of the suspension. During the suspension period, no funds from this award may be provided to the member site for new accruals, and no charges to the award for new accruals will be permitted.

The CTMB staff will review and provide advice regarding mechanisms established by the Research Base and its associated Research Base SDMC for quality control of therapeutic and diagnostic modalities employed in its trials. The CTMB staff reviews and approves the mechanisms established by the Research Base and its

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associated Research Base SDMC for study monitoring including its onsite auditing program. NCI DCP and NCI/CTEP and/or its contractor staff may attend, as observers, the onsite audits conducted by NCORP Research Base. The frequency of participation by an NCI representative as observer will be determined by the NCI.

Any data irregularities identified through quality control procedures or through the audit program that raise any suspicion of intentional misrepresentation of data must be immediately reported to CTMB and CTEP, NCI. The CTMB must be notified immediately by telephone [240-276-6545] of any findings suspicious and/or suggestive of intentional misrepresentation of data and or disregard for regulatory safeguards for any of the three (regulatory, pharmacy, and patient care) components of an audit. Similarly, any data irregularities identified through other quality control procedures suspicious and/or suggestive of intentional misrepresentation of data must be immediately reported to CTMB. It is the responsibility of NCORP Research Base, or CTSU to immediately notify CTMB when they learn of any significant irregularities or allegations related to scientific misconduct by a staff member or institution participating in NCORP clinical trials. It should be emphasized that the irregularity/misrepresentation does not need to be proven, a reasonable level of suspicion suffices for CTEP CTMB notification. It is also essential that involved individual(s) and/or institutions follow their own institutional misconduct procedures in these matters.

1.9b Cancer Care Delivery Research

NCI /DCCPS Program Directors will review quality control and monitoring procedures of the Research Bases including the on-site auditing program, and may attend on-site audits conducted by the Research Base or its NCI designee.

Each NCORP Research Base is responsible for ensuring that all community component cancer care delivery research sites have routine audits in accordance with the schedule proposed the Research Base and approved by the NCI and that the results of audits are reported to the NCI in accordance with the guidelines. In the event that the NCI determines that a Research Base member is failing to comply with regulatory auditing guidelines, the NCI may, in consultation with the Research Base,

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suspend the site immediately from participating in any NCORP study led by the Research Base or all NCORP studies regardless of the Research Base leading the study. The suspension will remain in effect until the Research Base conducts the required audit and the audit report or remedial action is accepted by the Research Base and the NCI.

NCI DCCPS and/or its contractor staff may attend, as observers, the onsite audits conducted by NCORP Research Base. The frequency of participation by an NCI representative as observer will be determined by the NCI.

Any data irregularities identified through quality control procedures or through the audit program that raise any suspicion of intentional misrepresentation of data must be immediately reported to NCI.

It is the responsibility of NCORP Research Base, or CTSU to immediately notify NCI when they learn of any significant irregularities or allegations related to scientific misconduct by a staff member or institution participating in NCORP clinical trials.

***1.10 Data Management and Analysis Review & Use of Standard
NCORP Tools and Services***

At the request of COPTRG, ORB or CTEP, the Biometric Research Branch (BRB) staff, in consultation with other NCI/DCTD staff, will review mechanisms established by the Research Base for data management and analysis. When deemed appropriate, COPTRG or ORB staff will make recommendations to ensure that data collection and management procedures are adequate for quality control and analysis, yet sufficiently simple to encourage maximum participation on NCORP studies and to avoid unnecessary expense. In addition, the NCI will have access to all Research Base data although the data remain the property of the awardee institution under the Cooperative Agreement. Data must also be available for external monitoring as required by NCI's agreement with the FDA relative to the NCI's responsibility as agent sponsor.

During the approval process for clinical trials and cancer care delivery research study protocols and amendments, NCI/DCCPS ensures that standard NCTN tools and services are used when applicable. To the extent that common data elements and tools are developed and adopted for cancer care delivery, efforts will be made to ensure compliance using standard tools. In addition, NCORP Research Base trial

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protocols will be periodically audited by NCI/DCP, DCCPS and DCTD to ensure that the tools related to common data elements are in compliance with the NCTN Program data dictionary for common data elements in caDSR. If issues with compliance are identified, the NCI/DCP and NCI/DCCPS will work with the Research Base to develop a corrective action plan.

1.11 Program Review, Strategy Sessions, and Federally Mandated Requirements

The NCORP Research Base will provide an annual progress report (PHS 2590) and other reports as needed. DCP/COPTRG and/or DCCPS/ORB Program Directors may perform annual visits as well as periodic site visits as part of the program assessment process. Quarterly accrual reports by clinical trial or other study type will also be assessed. DCP/COPTRG and/or DCCPS/ORB Program Directors, and DCTD staff, will also review mechanisms established by each Research Base to meet the Department of Health and Human Services (DHHS)/Public Health Service (PHS) regulations for the protection of human subjects and FDA requirements for the conduct of research using investigational agents. Each NCORP Research Base will be evaluated on its progress in designing, developing, implementing, and completing cancer prevention, control and care delivery studies.

Funding for each NCORP Research Base will be adjusted annually based upon the planned scope of work and availability of funds.

NCI Program Directors will sponsor strategy sessions when indicated.

2. NCI Responsibilities Related to NCORP Community Sites and Minority/Underserved Community Sites

2.1 Scientific and Administrative Program Directors & Activities

The NCORP Director is the NIH/NCI Program Official responsible for the routine scientific and programmatic stewardship of all the awards for NCORP and will be named in the award notice. The NCORP Associate Director will be named in the award notice for cancer care delivery research components of NCORP as he/she has major responsibilities in assisting the NCORP Director for the scientific and programmatic stewardship of the awards.

Each NCORP Community Site will have a staff physician, nurse, and/or other professional staff member from DCP/COPTRG or DCCPS/ORB assigned to them as Program Director for scientific and administrative matters. The Program Director monitors the Community Site's progress, attends their meetings, and is responsible for understanding

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the Community Site's repertoire of studies and scientific activities, including areas of special interest, expertise, and unique resources.

The Program Director is also responsible for providing the NCORP Director and Associate Director with ongoing assessments of the key component's activity from a scientific and administrative perspective, including general information on its budget. Primary responsibility for the budgets of NCORP Community Sites, however, resides with the NCORP Director who is assisted by the DCP/COPTRG Senior Program Specialist. (See Parts 2 and 3 of these Guidelines for information on budgetary issues for the key components of NCORP related to new applications as well as non-competing continuing applications.)

The DCP/COPTRG Senior Program Specialist may be delegated by the NCORP Director to request and receive budgetary and administrative materials from the Community Sites on either an ad hoc or routine basis. The DCP/COPTRG Senior Program Specialist will frequently perform liaison activities concerning budgetary and administrative matters on behalf of the responsible NCI Program Director, interfacing primarily with the primary Administrators for the Community Sites.

2.2 Attendance at NCORP Community Site Meetings

NCI/DCP and NCI/DCCPS Program Directors and other NCI staff, as designated by NCORP Director and Associate Director, will attend core NCORP Community Site meetings. As part of their liaison responsibilities, Program Directors may also attend Community Site Executive Committee meetings.

2.3 Review of Clinical Trials and Other Studies in NCORP Network for Crediting

All clinical trials and other study designs originating at NCORP Research Bases must be reviewed and approved by the Protocol Review Committee of the Division of Cancer Prevention (DCP) or Division of Cancer Treatment and Diagnosis (DCTD), as appropriate, in order for an NCORP Community Site to receive credit for participant accruals to such studies.

2.4 On-Site Auditing

The NCI/DCP and NCI/DCCPS Program Directors or other NCI-designated entity may conduct periodic on-site audits of NCORP Community Sites. NCI/DCP, NCI/DCCPS and/or CTMB/CTEP will review and advise on mechanisms for the on-site auditing program. DCP/CTEP representatives (or a designee) may attend on-site audits of NCORP Community Sites conducted by NCORP Research Bases.

2.5 Data Management and Access

The NCI/DCP and NCI/DCCPS Program Director(s) will have access to all data generated under this award. The Program Director will periodically review the data management procedures of NCORP Community Site.

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(NCORP)**

**Budget Levels for Per Case Management Funding & Budget Adjustments for NCORP: NCI/DCP and
DCCPS Staff Responsibilities**

2.6 *Investigational Drug Management*

RAB/PMB/CTEP/DCTD and DCP/COPTRG/CADRG will advise investigators of specific requirements and updates in requirements about investigational drug management that the FDA and NCI may mandate.

2.7 *NCORP Community Site Organizational Changes*

In addition to standard NIH procedures for approval of organizational changes, such as changes of the PD(s)/PI(s), the NCI Program staff members will review other organizational change requests and provide a written response. Organizational changes requiring NCI approval are outlined in "Guidelines for Approval of NCORP Organizational Changes," available at <http://prevention.cancer.gov/ncorp>.

2.8 *Program Review and Federally Mandated Requirements*

The NCI/DCP Program Director will provide a suggested format for NCORP Community Site awardee's initial and renewal application as well as the annual report (PHS 2590). NCI Program Director(s) review of each NCORP Community Site awardee will include: 1) An analysis of NCORP Community Site awardee's annual report, with follow-up of noted problems and recommendations for improvement; 2) periodic site visits (see 1.4 above); 3) review of NCORP Research Base evaluations of the affiliated NCORP Community Site.

NCI DCP, DCCPS and DCTD staff members review mechanisms established by each NCORP Community Site awardee to meet the Department of Health and Human Services (DHHS)/Public Health Service (PHS) regulations for the protection of human subjects and FDA requirements for the conduct of research using investigational agents.

NCI/DCP may adjust funding annually based on the planned scope and availability of funding. The NCI may also adjust funding, withhold support, suspend or terminate the award, if NCORP Community Site awardee fails to meet the performance requirements set forth in the Terms and Conditions of Award in the FOA, and/or the level of performance changes dramatically.

III. Budget Levels for Per Case Management Funding & Budget Adjustments for NCORP

The final decision regarding funding for the all NCORP awards, administrative supplements, and amounts selected for all "per case management" funding, including "special per case management" funding and "biospecimen per case management" funding for specific trials, rests with the NCI/DCP and/or DCCPS. NCI/DCP also sets the threshold levels for accrual for "high-performance" sites for NCORP (i.e., Community and Minority/Underserved Community Sites, depending on the availability of funding).

Changes in Awardee Institution for Any Key Component of NCORP:

IV. Changes in Principal Investigator(s) for Any Key Component of NCORP

The NCORP Director and/or Associate Director or his/her NCI/DCP or DCCPS Program Director designee must approve any proposed changes in the Principal Investigator (PI) for any key component for NCORP under the Cooperative Agreement. The institution's business office should forward the name of the proposed Principal Investigator in a memorandum to the NCORP Director and/or Associate Director requesting approval, with a copy to the NCI/DCP Senior Program Specialist. The curriculum vitae (CV) of the proposed Principal Investigator should be included as an attachment. The memorandum should be countersigned by the current Principal Investigator (if available), the business official who has responsibility to sign for the grant, and the proposed Principal Investigator.

V. Changes in Awardee Institution for Any Key Component of NCORP

Only under exceptional circumstances will NCI permit transfer of a Cooperative Agreement from one institution to another for NCORP Research Bases as the recipient institution would not have undergone peer review. Any such request should be approved in accordance with the Research Base's Constitution and By-laws (e.g., approval required by an oversight committee such as its Board of Governors or Executive Committee). The responsible Lead NCORP Program Director and the NCI/DCP Senior Program Specialist should be consulted for further advice if the Research Base or Community Site contemplates such a transfer request. For institutional changes affecting cancer care delivery research, responsible NCI/DCCPS Program Director also should be consulted. Any such request, if accepted, will require a full PHS 398 application or electronic SF424 Research & Related (R&R) application, a detailed plan regarding policies and procedures related to personnel issues, resources, etc., and approval and oversight by the responsible NCORP Director. NCI Program staff will review organizational change requests and provide a written response.

Organizational changes requiring NCI approval are outlined in "Guidelines for Approval of NCORP Organizational Changes," available at <http://ccop.cancer.gov/trials-resources/resources/guidelines-organizational-changes>.

**Part 1: Overview of the National Cancer Institute Community Oncology Research Program
(NCORP)**

Joint Responsibilities (Key Components NCORP, NCI/DCP and NCI DCCPS): Data and Safety
Monitoring Boards (Data Monitoring Committees)

**VI. Joint Responsibilities (Key Components NCORP, NCI/DCP
and NCI DCCPS)**

A. General Study Development and Conduct

Because of the significant resource, regulatory, and general administrative issues involved in NCORP key component activities and to ensure required compliance with other federal regulations and federal agencies, NCORP Research Bases should collaborate closely with NCI/DCP and DCCPS staff. This collaboration should occur early on in the development of studies as well as in the development of general research strategies and new initiatives. In particular, when new avenues of cancer prevention or symptom management involving investigational drugs are pursued, the trial should be designed such that the clinical information obtained should be acceptable to the FDA for inclusion in a potential licensing application. Therefore, the NCI/DCP staff and the Research Base should work collaboratively to develop protocols meeting that standard. When intervention studies have indications for Medicare participation, the Research Base should work collaboratively with the NCI to develop protocols meeting these requirements or pursuing the option to obtain waivers for these requirements. All parties (Research Bases, NCI/DCP staff, and company collaborators should be involved in any conference calls and/or meeting involving the FDA during the development and conduct of any approved NCORP trial with licensing potential, regardless of whether the study is being conducted under DCP IND or a Research Base IND in order to ensure that all sponsors are involved in discussion regarding the trial.

Both the Research Bases and NCI/DCP and DCCPS share the responsibility to ensure that study proposals are reviewed/evaluated, protocols developed, and trials activated in a timely manner. As it relates to clinical trials, the timelines established and approved by the Operational Efficiency Working Group (OEWG), including target and absolute deadlines for opening trials to patient enrollment. A description of the OEWG process, requirements, and required timelines are available at:
<http://ctep.cancer.gov/SpotlightOn/OEWG.htm>.

Both the Research Bases and NCI/DCP and DCCPS also share the responsibility to collaborate on initiatives to promote accrual to NCORP trials and cancer care delivery research intervention studies.

B. Data and Safety Monitoring Boards (Data Monitoring Committees)

The appropriate conduct of NCORP Research Base Data Safety and Monitoring Boards (DSMBs), sometimes called Data Monitoring Committees (DMCs), is a collaborative responsibility of the Research Base (Operations Center and associated Statistics and Data Management Center) and NCI/DCP staff. NCORP Research Bases that are funded NCTN Network Groups may augment the NCTN Network Group DSMBs/DMCs and Data Safety and Monitoring Policy to address the types of clinical trials/studies conducted by the Research Base. Information on the NCI/CTEP policy for DSMBs/DMCs is available in Part 4 – Appendices – Section VIII of these

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Joint Responsibilities (Key Components NCORP, NCI/DCP and NCI DCCPS): Development of Collaborative Trials and International Trials

Guidelines. The Research Base's Data and Safety Monitoring Policy must be submitted to and approved by the Lead NCORP Program Director. All relevant DSMB members must be approved by the Lead NCORP Program Director prior to their inclusion in DSMB meetings. Any changes to the Research Base DSMB policy and/or membership must be reviewed and approved by the Lead NCTN Program Director prior to implementation. The Lead NCORP Program Director also names the NCI/DCP staff who represent NCI/DCP as non-voting members on the Research Base's DSMB. If the Research Base DSMB includes oversight of studies funded by the Division of Cancer Treatment and Diagnosis all changes in membership and policy are also reviewed by the appropriate staff in DCTD as applicable and DCTD also names the non-voting NCI/DCTD staff person to represent the Division on the DSMB.

C. Development of Collaborative Trials and International Trials

The following information applies only to NCTN Network Groups that are also funded as NCORP Research Bases. Cancer care delivery research will not be conducted at international sites.

The Clinical Investigations Branch staff at CTEP work with the NCTN Network Groups to facilitate international participation in trials when appropriate. When institutions outside the U.S. are members of a U.S. Network Group and wish to participate in a U.S. Group Trial, the institution and its investigators must meet ALL the same Network Group membership requirements as U.S. institutional members and their associated investigators, including being audited by the Network Group per CTMB guidelines for international Participating Sites, filing FDA 1572 Forms, etc. However, when trials call for collaboration with a separate international clinical trial organization for its participation in a U.S. Network Group trial, there are varying degrees of logistical and regulatory complexity involved, depending on a number of factors. In these cases, it is critical that proposals for large-scale international trials be discussed with DCP/COPTRG and CTEP/CIB staff in advance for general advice and guidance regarding whether the advantages of international collaboration will outweigh the expected resource costs.

Network Group Operations Centers are required to have a binding collaborative agreement in place with the international clinical trial organization that addresses the major components of clinical trial conduct by the international organization to ensure that the conduct is consistent with all appropriate federal and other appropriate regulations for the clinical research trial. This agreement must be reviewed and approved by the Lead NCTN Program Director in consultation with the Associate Director of CTEP and the Chief, CTEP Regulatory Affairs Branch, and all appropriate U.S. State Department approvals must be in place for countries that will be participating in the research as well as other appropriate approvals (e.g., company partner approvals for trials being conducted under an NCI/DCTD binding collaborative agreement or CRADA).

With respect to participation of U.S. Network Groups and NCORP Research Bases led by a non-U.S. organization (other than the Canadian

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Joint Responsibilities (Key Components NCORP, NCI/DCP and NCI DCCPS): Collective Management of NCORP

Collaborating Clinical Trials Network of the NCTN), there are also numerous logistical, regulatory, and company-sponsor issues that must be addressed in addition to approval of the non-U.S. trial by the NCI via the appropriate NCI Scientific Steering Committee (if applicable).

In addition, the lead U.S. Network Group Operations Center that is the primary or lead sponsor for the trial in the U.S. must have U.S. State Department approvals in place for countries that will be participating in the research even though federal funds will only be used to support the participants from the NCTN/NCORP Program enrolling patients on study. The research agreement between the U.S. Network Group Operations Center that is the primary or lead sponsor for the trial in the U.S. and the international organization leading the trial that governs the conduct of the study must be reviewed and approved by the Lead NCTN/NCORP Program Director in consultation with NCORP senior leadership.

A guidance document from NCI/DCTD/CTEP entitled, *Cooperative Group Guidelines for the Development, Conduct and Analysis of Clinical Trials with International Collaborating Institutions*, is available on the CTEP website at: http://ctep.cancer.gov/guidelines/nci_clin_intl_guidelines.pdf. This document addresses the various regulatory issues involved in the conduct of international trials that involve participation/leadership of Network Groups under the NCTN Program.

D. Collective Management of NCORP

In order to provide for collaboration and coordination of policies and procedures for NCORP, collective management is needed. To achieve this goal, a core collective management team (i.e., NCORP Leadership Management Committee) composed of 1 senior leadership representative from each of NCORP Research Bases and key NCI program leadership from relevant Divisions and Centers to discuss major policy issues and address concerns about NCORP. The Committee will make recommendations to senior NCI leadership on the Program. It is anticipated that the Committee will meet on at least a quarterly basis by teleconference and/or in-person. Additional representatives from NCORP may be invited to participate in meetings depending on the issues to be discussed. It is also anticipated that there may be meetings held specific to NCORP Directors of Operations/Group Administrators on a periodic basis to discuss significant issues, as appropriate.

Specific areas that will require recommendations from NCORP Leadership Management Committee include but are not limited to the following:

- Address important coordination issues between the NCTN and NCORP
- Address scientific coordination between NCORP clinical trials and cancer care delivery research studies

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Joint Responsibilities (Key Components NCORP, NCI/DCP and NCI DCCPS): E. Network-Wide Common Services, Tools, and Resources

- Address recommendations from the NCI Clinical Trials and Translational Research Advisory Committee (CTAC) on strategic directions for NCORP Program
- Establishment and conduct of Toxicity-specific Working Groups
- Establishment and coordination of a standardized approach for health-related quality of life and patient-reported outcome endpoints as secondary on treatment trials and primary endpoints on cancer control trials

E. Network-Wide Common Services, Tools, and Resources

Research Bases are **required** to use standard NCORP tools and services for all NCORP studies including, but not limited to: (a) NCTN information system for tracking biospecimen collection from NCTN trials (in development); (b) the NCI Common Terminology Criteria for Adverse Events (CTCAE); and (c) review of all pediatric phase 2 and phase 3 trials by the NCI Pediatric Central Institutional Review Board (CIRB). NCORP Cancer Center Research Bases are expected to use the tools and services by the end of the initial five year funding cycle.

During the approval process for study protocols and amendments, NCI/DCP ensures that standard NCORP tools and services are used. Clinical trial Research Base trial protocols will be periodically audited by NCI/DCP to ensure that the tools related to common data elements in compliance with NCORP approved sections of the data dictionary for common data elements in caDSR are used in the data collection instruments for NCORP trials. If issues with compliance are identified, the NCI/DCP will work with the Network Research Base to develop a corrective action plan. In addition, NCORP Research Base cancer care delivery research protocols will be periodically audited by NCI/DCP, DCCPS and DCTD to ensure that the tools related to common data elements are in compliance with the NCTN Program approved sections of the data dictionary for common data elements in caDSR used for NCORP cancer care delivery research studies. Throughout the funding, use of additional tools may be required based on availability. Research Bases also will be required to implement standard NCORP data collection tools approved by the NCORP cancer care delivery Coordinating Committee should any be instituted during the NCORP award period.

It is strongly encouraged that the Cancer Trials Support Unit (CTSU) be utilized for all NCORP trials. NCORP trials using CTSU must also use the NCTN Oncology Patient Enrollment Network (OPEN) and Regulatory Support Services (RSS) for central registration and randomization of patients onto NCORP trials. It is anticipated that use of the CTSU will become a future requirement for NCORP.

VII. Appeals Process for Decisions Regarding Study Proposals & Types of Studies Performed by NCORP

This appeal process is only for disagreements related to scientific merit decisions made on study proposals for NCORP or the programmatic definition of study types supported under NCORP.

A. Decisions on Study Proposals

The appeals process for decisions related to study proposals supported under NCORP (including both intervention and non-intervention studies) is described below.

For NCORP concepts evaluated by NCI Scientific Steering Committees or the DCP Concept Review Committee, or the DCCPS Concept Review Committee that are not approved for development based on scientific merit, the Research Base may “appeal” the decision to the Director, Division of Cancer Prevention, if the Research Base believes that there were factual errors in the evaluation that led to the disapproval. If the Director agrees with the appeal request by the Research Base, the Director will direct the appropriate NCI Steering Committee, DCP or DCCPS Concept Review Committee to re-evaluate the study proposal. The result of the re-evaluation will be considered final.

Any approval of a concept, even after appeal, is subject to feasibility/resource considerations as determined by NCI/DCP.

VIII. Other NCI Administrative Considerations

A. Program Staff Administration of NCORP

Within NCI/DCP, major scientific policy and programmatic decisions concerning NCORP are made only after appropriate consultation with and involvement by the NCORP Director, the NCORP Associate Director, the Program Directors, and NCI/DCP Branch Chiefs and Program Chiefs that are involved in the Program, and the Deputy Director, DCP, and DCCPS leadership as necessary and appropriate. Routine programmatic administration is the responsibility of NCORP Director, who assures uniformity of implementation across the various key components in conjunction with the Associate Director and Program Director.

The NCORP Director or his/her designee has responsibility for addressing and approving non-competitive award (Type 5) budget requests, any supplemental budget requests, and new/competitive award (Type 1) budgets, as well as future Type 2 applications. NCORP Director will administer these tasks in conjunction with the Grants Management Specialist in the Office of Grants Administration (OGA) and will be assisted by the NCORP Associate Director and Program Directors of NCORP as well as the NCI/DCP Senior Program Specialist for the Program.

B. Senior Program Specialist for NCORP

The NCI/DCP Senior Program Specialist for NCORP works closely with the NCORP Director and NCORP Associate Director in reviewing administrative materials supporting Research Base requests, performing budget analyses, and facilitating the completion of action items involving coordination between NCI/DCP and NCI/DCCPS, the NCI Office of Grants Administration (OGA), and the awardees under the Program. The NCI/DCP Senior Program Specialist exchanges information with the Research Base Directors of Operations for the key components of NCORP and OGA staff on administrative changes and priorities.

C. NCI Office of Grants Administration (OGA)

The Grants Management Specialist for the NCI Office of Grants Administration (OGA) is responsible for the fiscal and administrative aspects of each application and award. The Grants Management Specialist for OGA works closely with the NCORP Director, NCORP Associate Director and NCI/DCP Senior Program Specialist to assure that appropriate science is funded in accordance with applicable laws, regulations, policies, and peer review recommendations to the extent that the budget allows and NCI priorities dictate.

D. Miscellaneous Budgetary Considerations

1. Carryover Requests

Carry-over requests will be entertained in situations where circumstances prevented funding from being spent during the budget period for which it was provided and where funding is not replicated in the current budget year for an ongoing expense.

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(NCORP)

Other NCI Administrative Considerations: ***Miscellaneous Budgetary Considerations***

2. Requests for Non-competing Supplemental Funding

Informal discussions about the possibility of receiving non-competing supplemental funding for special needs and/or additional funding to cover data collection and management and biospecimen collection on a per case basis may be initiated by the awardee for the key component of NCORP. However, formal requests must be made for funding to be received and must always be countersigned by the business official responsible for the Cooperative Agreement/grant and the Principal Investigator(s). Electronic facsimile signatures on documents transmitted via email are acceptable. Most requests, however, will require the use of a Form PHS 398/SF424 or PHS 2590 to capture the details of the requested budget. The original should be sent to the NCORP Director and the NCORP Associate Director when involving cancer care delivery research, in care of the NCI/DCP Senior Program Specialist.

Part 2: Guidelines for Submission of Competing New Applications & Description of Review

Process

Pre-Application Consultation and Application Submission Instructions: ***General Considerations and Due Dates***

Part 2: Guidelines for Submission of Competing New Applications & Description of Review Process

I. Pre-Application Consultation and Application Submission Instructions

A. General Considerations and Due Dates

All competing new applications (Type 1) for support through the NCI Community Oncology Research Program (NCORP) must be submitted under the appropriate Funding Opportunity Announcement (FOA) for each of the three (3) key components of the Program as listed below. The FOAs contain essential information on various aspects of the components including the eligibility requirements for the applicant institution/organization and Principal Investigator(s).

NCORP Program Key Component	Funding Opportunity Announcement (FOA)
NCORP Research Bases	<u>RFA-CA-13-012 (UM1)</u>
NCORP Community Sites	<u>RFA-CA-13-013 (UM1)</u>
NCORP Minority/Underserved Community Sites	<u>RFA-CA-13-014 (UM1)</u>

All new applications must be prepared using the most currently revised PHS 398 research grant application instructions and forms or SF424 (Research & Related [R&R]) application once this electronic application replaces the PHS 398 for the Cooperative Agreements supported under this Program (i.e., NCORP Research Bases, Community Sites and Minority/Underserved Community Sites). The major components of the PHS 398 as described in these Guidelines for NCORP are retained in the SF424. Hence, applicants should follow the same instructions provided in these Guidelines regardless of whether they are using the PHS 398 or SF424 application. The PHS 398 is available at: <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact: **Grants Info**, Telephone (301) 435-0714, **Email:** GrantsInfo@nih.gov. Once the SF424 is required for applications submitted for NCORP, applicants will be notified by the NCI/DCP Program Specialist and applicants should use the appropriate NIH website references available at: <http://grants.nih.gov/grants/funding/424/index.htm> to access information regarding submission of the SF424.

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Pre-Application Consultation and Application Submission Instructions: ***General Considerations and Due Dates***

It should be noted, however, that the standard instructions included in the PHS 398 and SF424 applications are designed primarily for individual research projects, and do not address the unique goals and policies of the NCI Community Oncology Research Program (NCORP). **These Guidelines are only meant to supplement the PHS 398/SF424 instructions, except where it is explicitly noted that these Guidelines are replacing or supplanting instructions in the PHS 398/SF424 application (e.g., the format for the research plan is different for these applications). If an issue is not explicitly included in these Guidelines, then applicants should follow the information and guidance given in the PHS 398/SF424.**

Applications not prepared using the current version of the PHS 398 application forms (or SF424 electronic application when it replaces the PHS 398) or not adhering to the format and preparation instructions contained in these Guidelines and the appropriate NCI NCORP Funding Opportunities Announcement (FOA) may be returned without review or just not reviewed. Organizations submitting new applications for any of the key components of the NCORP supported under the Program **MUST** apply for five (5) years of support. Applications requesting less or more than 5 years of support may be returned without review.

The receipt dates & review schedule for all new competing applications for 5 years of support should be submitted in response to the Funding Opportunities Announcements for the key components of NCORP are summarized below:

Application Submission & Review Activity	Due Date
Pre-consultation with NCI/DCP	3-4 weeks <u>after the Request for Applications are published</u>
Letter of Intent Due Date	December 8, 2013
Application Due Date	January 8, 2013
Post Submission Application Materials	30 Days Prior to Scientific Merit Review Meeting
Scientific	http://grants1.nih.gov/grants/funding/submissionsche

Part 2: Guidelines for Submission of Competing New Applications & Description of Review

Process

Pre-Application Consultation and Application Submission Instructions: ***Initial Communications and Letter of Intent***

Merit Review	dule.htm - reviewandaward
Advisory Council Review (NCAB)	June 2014
Earliest Start Date	September 2014
Just-in-Time Information	Prior to Start Date

B. Initial Communications and Letter of Intent

Initial Communications with NCI Staff – approximately 3 to 4 weeks after the Request for Applications are published in the NIH Guide to Grants and Contracts (<http://grants.nih.gov/grants/guide/index.html>). NCI staff will arrange pre-application teleconferences to address questions from investigators about the NCORP Request for Applications as well as the application process. Relevant NCI staff from DCP, DCCPS, DCTD, CRCHD and the Division of Extramural Activities will participate in the teleconferences. Separate teleconferences will be convened for each of the 3 RFAs for key components of NCORP. Information about the pre-application teleconferences <http://prevention.cancer.gov/ncorp>

Letter of Intent – 30 Days Before Application Due Date:

Although a Letter of Intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NCI staff to estimate the potential review workload and plan the review. By the date listed in the table provided under “**General Considerations and Due Dates**” in **Part 2 – Section I.A in these Guidelines**, prospective applicants are asked to submit a Letter of Intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the Program Director(s)/Principal Investigator(s)
- Names of other key personnel
- Participating institutions
- Number and title of the Funding Opportunity Announcement/Request for Application

The Letter of Intent should be sent to:

NCORP Lead Program Director:
Worta McCaskill-Stevens, MD, MS

Part 2: Guidelines for Submission of Competing New Applications & Description of Review

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Pre-Application Consultation and Application Submission Instructions: **Appendix Material for All**
Key Components of NCORP

Community Oncology and Prevention Trials Research Group
National Cancer Institute
9609 Medical Center Drive, Room 5E
Bethesda, MD 20892- (for U.S. Postal Service regular or Express Mail)
Rockville, MD 20850 (for non-USPS delivery)
Telephone: 240-276-7050
Email: mccaskiw@mail.nih.gov

C. Application Submission Procedures

Applications must be prepared using the PHS 398 research grant application forms and instructions (unless they have converted to electronic submission) for preparing a research grant application. Submit a signed, typewritten original of the application, including the checklist, and three (3) signed photocopies in one package to the Center for Scientific Review at the address listed below. **The original must be signed by the Project Director/Principal Investigator (PD(S)/PI(S)) and an authorized organizational or institutional official.**

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

At the time of submission, two (2) identical, single-sided paper copies of the original application and one (1) CD containing appendix material (if allowed for the NCORP key component) must be sent to the address listed below. Please Note: One of the two copies of the application sent to the NCI Referral Office may be a CD with a bookmarked PDF file (as outlined in the PHS 398). All appendix material (if allowed for the NCORP key component) must be prepared as bookmarked PDF files on a CD following the instructions in the PHS 398 form.

Referral Officer
Division of Extramural Activities
National Cancer Institute
9609 Medical Center Drive,
Bethesda, MD 20892- (for U.S. Postal Service regular or express mail)
Rockville, MD 20850 (for non-USPS delivery)
Telephone: (240)276-
FAX: (249)276-
Email: ncirefof@dea.nci.nih.gov

D. Appendix Material for All Key Components of NCORP

Per the NIH/NCI policy on what may be submitted as appendix materials (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-077.html>), **the information provided below specifies if appendix materials are allowed as part of the application for the key component of NCORP**

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Pre-Application Consultation and Application Submission Instructions: **Appendix Material for All**
Key Components of NCORP

as well as the type of appendix material that may be included. All appendix materials for paper applications submitted on the PHS 398 form must be submitted as book marked PDF files on CDs. A summary listing of all the items included in the appendix is encouraged but not required. When including a summary, it should be the first file on the CD.

Follow the standard instructions for preparing the CDs:

- Use PDF format only. The files should be prepared as PDF version no higher than 1.4 for compatibility with NIH programs and software.
- Where possible, applicants should avoid creating PDF files from scanned documents. NIH recommends producing the documents electronically using text or word-processing software and then converting the document to PDF format. Scanned document images should be checked for legibility.
- Label each disk with the date, Principal Investigator's Name, Grant Number (if available), grant title, and applicant institution.
- If burning CD-ROM disks on a Mac, select the ISO 9660 format.
- Do not use compression techniques for the electronic files.
- Do not use password protection, encryption, digital signature and/or digital certification in the PDF files.

Applications for key components of NCORP are scanned by central NIH offices to produce black and white images and black and white double sided copies for the reviewers. Figures in the application that do not reproduce well in black and white may be included in the application and allowed Appendix material. However, all figures included in the appendix material must be included in the application, although they may be reduced in size in the application. Images not included in the application cannot be included in the appendix.

If your application contains a large number of color illustrations or charts and graphs that will not reproduce well in black and white, you may also submit a CD with a bookmarked PDF file of the entire application as one of the two copies of the application sent to the NCI Referral Office on the due date. Such CDs will be accepted only at the time of application submission. The PDF file should be bookmarked at major subdivisions of the application so that reviewers can navigate through the file and find individual components easily. The files should be saved as PDF version no higher than 1.4 for compatibility with NIH programs and software.

Appendix materials must be included with the copies of the application sent to the NCI Referral Office on the due date as specified above in Part 2 – Section I.C of these Guidelines. Additional copies of the collated sets of Appendix material may be requested by the Scientific Review Officer (SRO) from the Division

Part 2: Guidelines for Submission of Competing New Applications & Description of Review

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Pre-Application Consultation and Application Submission Instructions: ***Notification of International Involvement in NCORP Trials***

of Extramural for the peer review of the application and the number of additional copies and timing of submission should be discussed at the time of the pre-application consultation with NCI Program Staff and the SRO. Appendix material cannot be used to circumvent page limitations of the research plan.

All the key components of NCORP can provide the following information (and only the following information) in the appendix material for their respective applications as described below.

Applicants may submit up to 3 of the following types of publications:

- Manuscripts and/or abstracts accepted for publication but not yet published that are referenced in the Research Plan of the application.
- Published manuscripts and/or abstracts that are referenced in the Research Plan of the application **only** when a free, online, publicly available journal link is not available.
- Patents materials directly relevant to the application.

Other Information:

- Paper PHS 398 applications **only** may include full-sized glossy photographs of material such as electron micrographs or gels in the Appendix; however, an image of each (may be reduced in size but readily legible) must also be included within the page limitations of the Research Plan.
- Any additional appendix material that is allowed for a specific key component of NCORP will be listed in the corresponding "Appendix Material and Post Submission Materials" sub-section in Part 2. II of these Guidelines for that key component.

E. Notification of International Involvement in NCORP Trials

The NCORP key component should alert the NCI/DCP Senior Program Specialist when the new competing application involves any international (non-US) component. In such cases, advance clearance from the U.S. Department of State is required for each non-US component prior to the award. The information required by U.S. Department of State is listed below (this information should also include all non-US subcontracts).

- Estimated annual Total Cost dollar award for the non-US component
- Name, organization, city, and country of the International (non-US) Principal or Collaborating Investigator(s)
- Bio-sketch and Curriculum Vitae (CV) for both the domestic Principal Investigator and the international Principal Investigator

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Pre-Application Consultation and Application Submission Instructions: ***Post Submission Materials***

- OHRP assurance number (i.e., Federal wide Assurance number) for the non-US component

F. Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030 **Note:** Because applications submitted in response to the Request for Applications (RFAs)/Funding Opportunity Announcements (FOAs) for all the key components of NCORP have only one due date, applicants may submit materials per the exceptions list in NOT-OD-13-030 using the specified page limits (see: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-030.html>).

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New Applications Format and Budget Considerations: *B. NCORP* Research Base Application

II. New Applications Format and Budget Considerations

A. General Information for NCORP Components

All applications for key components of NCORP must follow the PHS 398/SF424 format for new applications, including formatting and page limitations except as modified below. The applications should describe the scientific and administrative experience of key personnel and should include and follow the PHS 398/SF424 instructions for Biographical Sketches and Other Support information (including support for clinical trials and cancer care delivery research activities). In the section entitled "Key Personnel" in the PHS 398/SF424, it is imperative that applicants list all individuals participating in the scientific execution of the main activities of the NCORP component in the format specified (i.e., name, organization [their institutional affiliation], and role on the project), including those with no requested salary support. Under "Role on the Project", indicate how the individual will function with regard to activities of the NCORP Component.

A roster of Key Personnel should be included with each application. Key Personnel will usually include the PI (and multiple PIs, if applicable), other significant scientific, technical and administrative officers as well as major committee chairs and vice-chairs. Consultants should also be included if they meet the definition of "Key Personnel." Applicants must ensure the list of Key Personnel is complete, and may use as many continuation pages as necessary. Although information on "Other support" is also required for all Key Personnel listed on all applications that are to receive grant awards, information on "Other Support" should NOT be submitted with the application. Rather, NIH will request complete and up to date "Other Support" information from applicants at an appropriate time following peer review. The NIH's scientific program and grants management staff will review this information prior to award (see "Just-in-Time" information in this section of the Guidelines).

B. NCORP Research Base Application

Specific instructions are provided on the following pages for the Research Base application. In general, except where noted below, all NCORP Research Base applications should conform to the instructions provided in the PHS 398/SF424.

Total Budget for a NCORP Research Base: The budget of a Research Base is divided into two parts: (1) a clinical trials budget which includes costs for cancer prevention, control and screening/post-treatment surveillance clinical trials as well as health-related quality of life (HRQOL) studies embedded within treatment and imaging trials and (2) a cancer care delivery research budget. A separate PHS 398/SF424 is required for each part. During the start-up and initial phase of NCORP the expected relative balance in level of effort between clinical trials and cancer care delivery research will be approximately 90% and 10%, respectively, for a given Research Base. However, funding from other sources can be used to augment the cancer care delivery research efforts.

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The clinical trials budget has two elements: (1) infrastructure costs for developing, conducting and analyzing NCORP clinical trials and HRQOL studies and (2) costs for reimbursing member institutions/sites that are not funded as a NCORP Community Site or Minority/Underserved Community Site (hereinafter referred to as "institutional members") for data collection and management and biospecimen collection associated with subject enrollment to NCORP clinical trials and HRQOL studies ("per case management" costs). The total cost infrastructure budget is dependent on the projected accrual to clinical trials and HRQOL studies led by the Research Base and the total cost per case management budget is dependent on projected accrual by the Research Base's institutional members to the clinical trials and HRQOL studies that it leads as well as to those led by other Research Bases that the institutional member is expected to credit to the applicant Research Base.

The NCORP Research Base is encouraged but not required to submit a Common Budget Outline (see Part 4: Appendices – Section IX) for the clinical trials portion of its budget as part of its application.

Rationale for the Common Budget Outline: The Common Budget Outline was designed to provide budget information in a standard format that allows the reviewers to understand how the total Research Base clinical trials budget is allocated among the various activities and facilitates comparison of budgets across Research Bases.

The cancer care delivery research budget has two elements: (1) costs for the scientific and statistical leadership, data systems/informatics and management infrastructure necessary to develop, conduct and analyze cancer care delivery research studies ("infrastructure costs") and (2) costs to cover study operations, statistical analysis, data management, quality control, study monitoring and auditing for studies led by the Research Base ("study-specific costs"). No per case management costs for institutional members should be budgeted as only NCORP Community Sites and Minority/Underserved Community Sites will be funded to participate in cancer care delivery research studies.

Because cancer care delivery research was not a focus of activity under the previous CCOP Research Base awards, the expectation is that the balance of infrastructure costs versus study specific costs will evolve over the course of the initial award period for each Research Base. In the initial award year, the proposed budget for a Research Base is expected to be 100% infrastructure costs as likely no cancer care delivery research studies will have yet been developed and approved and it will take time to develop a scientific, statistical, data systems, informatics and management infrastructure to support this area of research. Over the remaining award years, the percentage devoted to study specific costs is expected to increase, reaching a steady state of approximately 75% of the total Research Base budget for cancer care delivery research. The remaining 25% will continue to provide infrastructure support in terms of scientific and statistical leadership, data systems, informatics and management.

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New Applications Format and Budget Considerations: *B. NCORP* Research Base Application

1. Detailed Clinical Trials Budget for the Initial Budget Period

A budget for clinical trials should be provided.

1.1 Estimation of Total Cost Clinical Trials Budget Request

The total cost budget requested by the Research Base in its application for cancer prevention, control and screening/post-treatment surveillance clinical trials and HRQOL studies embedded within treatment and imaging trials should be based on the three elements described below. Suggested guidelines and examples are provided in Part 4 – Appendices – Section IV of these Guidelines:

Note: The information provided in the guidance on budget calculations are guidelines only and do not reflect a cap on costs that may be requested. Applicants should submit a budget that reflects the scope of work proposed. There is no requirement to use the sample guidance provided in the NCORP Program Guidelines nor is there any upper limit (i.e., budget cap) on clinical trials infrastructure or cancer care delivery.

- (1) An algorithm used to estimate the total infrastructure costs for developing and conducting NCORP clinical trials and HRQOL studies that the Research Base leads based on the projected accrual to the various categories of trials and studies listed in Part 4 – Appendices – Section IV; the projected accrual must be justified by the historical record of accrual to trials led by the applicant.
- (2) An algorithm used to estimate the per case management costs to cover data collection and management and biospecimen collection associated with subject enrollment to NCORP clinical trials and HRQOL studies by Research Base institutional members based on the projected accrual to the various categories of trials and studies listed in Part 4 – Appendices – Section IV by those members that will be credited to the Research Base but independent of which Research Base leads the trial or study
- (3) An algorithm used to estimate the total infrastructure costs for financial management of the per case management costs provided to Research Base institutional members

In preparing their budgets, applicants are encouraged to use the amounts specified in Part 4 – Appendices – Section IV of these Guidelines for the different categories of per case management funding. Applicants are not required to use the specific estimated ranges for infrastructure costs or per case financial management costs provided in Part 4 – Appendices – Section IV of these Guidelines and the estimated ranges used in the algorithm may be adjusted by the applicant to fit its particular funding needs.

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However, total cost Research Base budgets that include infrastructure costs and/or financial management costs based on estimated ranges that are in significant excess of the estimated ranges provided in Part 4 – Appendices – Section IV of these Guidelines are unlikely to be supported.

1.2 General Information

Since the organizational framework of each Research Base may be different, the budget for clinical trials should be presented in logical, discrete units, with specific budgets for each unit (e.g., support for scientific leadership, statistics, protocol development, data management, administration, regulatory oversight, “per case management” funding for institutional members). A specific budget page covering the Research Base’s quality assurance and study monitoring activities and onsite audit program must be included.

Funds for correlative science studies are not supported under NCORP and should not be included in the application.

Funding for integral and integrated laboratory and/or biomarker studies for NCORP trials can be covered by Biomarker, Informatics, Quality of Life Studies Funding Program (BIQSFP) awards (see information on the BIQSFP at: <http://bigsfpcancer.gov/>). Funding for all types of laboratory and/or biomarker studies can be provided through other sources of funding (e.g., R01/P01 grants, industry and charitable support), and potentially through administrative supplements for specific trials under the NCORP Cooperative Agreement.

1.3 Cost Categories

Once the Research Base applicant has determined the amount of its total cost budget request for clinical trials using the guidelines specified in Part 4 – Appendices – Section IV of these Guidelines, the applicant should provide a “level of effort” budget based on the budget categories described below. The categories listed below refer to those contained in the section of the PHS 398/SF424 pertaining to the detailed budget for the initial budget period.

1.3.1 Personnel: A clinical trials staffing plan for the Research Base, including position descriptions and qualifications should be provided. **NOTE:** Specific job descriptions and qualifications for funded personnel (administrative as well as scientific) should be covered in this budget section and not repeated in the research plan narrative. Precise justification for the amount of effort requested for each position is essential, including the following:

- **Research Base Leadership:** Research costs include the time and effort for the Research Base Chair or PI, any Vice-Chairs, Co-Chairs or co-PIs, as well as the time and

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effort for individuals for who have oversight responsibilities for scientific activities of the Research Base (e.g. Executive Medical Officers).

- **Scientific Leadership:** Research costs include the time and effort of scientific and administrative committee chairs and/or co-chairs as well as study chairs in developing the Research Base's research strategy for clinical trials and HRQOL studies and its repertoire of concepts and protocols as well as trial/study monitoring, analysis of results, and publication of research results in peer reviewed journals.
- **Scientific Services:** Research costs include the time and effort involved in providing scientific services such as toxicity, pathology, and symptom management assessment tool review specific to a Research Base study (i.e., not associated with conventional patient care or for educational purposes). Funding for integral and integrated laboratory and/or biomarker assessment for NCORP trials can be covered by BQSFP applications or other funding sources as described above.
- **Trial/Study Operations:** Research costs include the time and effort of the Research Base staff in development of concepts and protocols, including associated regulatory and quality assurance activities, as well as management of trials and studies after activation (e.g., protocol amendment processing).
- **Statistics:** Research costs include time and effort of the statistical staff in developing statistical designs and analysis plans for Research Base protocols as well as providing statistical analyses, interpretations, and conclusions with regard to study data and supporting required results reporting per federal regulation in www.clinicaltrials.gov as well as publication of those results in peer-reviewed journals.
- **Data Management:** Research costs include time and effort involved in the development of case report forms, central registration and randomization of patients onto clinical trials and HRQOL studies, collection and monitoring of primary patient data, compliance with relevant data reporting and other regulatory requirements, and associated quality assurance activities for all Research Base clinical trials and HRQOL studies.
- **Administration:** Research costs include the time and effort involved in the overall management/administration of the Research Base including finance and contracting staff, administrative IT support, and

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meeting/communications support.

- **Data and Safety Monitoring Boards (Required Funding in Application as Separate Line Item as Funding is Restricted for this Purpose):** Research costs include the time and effort involved in the overall management/administration of the Data and Safety Monitoring Boards for the Research Base's phase 3 and randomized phase 2 trials.
 - **Auditing (Required Funding in Application as Separate Line Item as Funding is Restricted for this Purpose):** Research costs include personnel costs and travel for the Research Base auditing program.
 - **Creation and Coordination of Trial Datasets for Data Sharing (Required Funding in Application as Separate Line Item as Funding is Restricted for this Purpose):** Personnel costs to support the creation and coordination of trial data sets for data sharing in a timely manner after the primary results of a clinical trial are published.
 - **Tumor Bank Coordination:** Personnel costs to support (a) coordination of the activities of the Research Base with those of any NCTN Tumor Bank or other repository that may store biospecimens for NCORP clinical trials and (b) providing for public access and reporting of research requests for and research activity with biospecimens from legacy chemoprevention and other CCOP trials.
- 1.3.2 *Consultant Costs:* Reasonable consultant costs are allowed if the consultant is contributing in a substantial way to development of the Research Base's clinical trials research strategy or the conduct of clinical trials or HRQOL studies although clear and quantifiable justification is required. Costs include travel, per-diem and consultant fees, if applicable and within institutional policy.
- 1.3.3 *Equipment:* Only those equipment items that are required for Research Base activities relevant to clinical trials and HRQOL studies should be included. Justification should include percent of time used for Research Base activities as well as necessity for purchase. The amount of funds requested should be based on percent of use.
- 1.3.4 *Supplies:* Research costs for appropriate supplies with quantitative justifications based on actual use should be provided.

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1.3.5 Travel: The importance of meetings to the achievement of the Research Base's overall research strategy is obvious, as is the necessity to maintain careful control over the size of this budget item. The budget for travel must be itemized and justified. It should include the following:

- Travel by Research Base leadership and/or investigators on behalf of the Research Base to the NCI and other national organizations where the clinical trial and HRQOL research results of the Research Base are presented or where the Research Base's clinical trial and HRQOL research strategies are discussed;
- Travel for Research Base clinical trial and HRQOL scientific and administrative committee members to committee meetings held separately from major Research Base meetings;
- Travel for clinical trial and HRQOL protocol chairs and others who must perform quality assurance functions away from their home institution;
- Travel for persons on Research Base staff who must attend the Research Base meetings due to their involvement in clinical trial and HRQOL research activities;
- Travel for the Research Base senior leadership to attend NCI/DCP Leadership Management Committee meetings for NCORP;
- Travel for the Research Base senior leadership to attend NCORP Cancer Care Delivery Research Coordinating Committee meetings (if applicable);
- Travel associated with onsite audit program for clinical trials and HRQOL studies (see Auditing under Personnel above); and
- A reasonable number of carefully justified trips for provisional Research Base members or other associated stakeholders (e.g., patient advocates) to attend Research Base meetings to encourage participation and assure input from all relevant modalities and stakeholders in clinical trial and HRQOL studies.

1.3.6 Alterations and Renovations: Costs for alterations and renovations are not allowable under NCORP.

1.3.7 Other Expenses: Research costs due to other expenses include those related to communication and information

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dissemination among components of the NCORP Research Base as well as with sites accruing participants to Research Base clinical trials and HRQOL studies. Also included are costs of equipment rental and maintenance (copiers, telephones, computers), postage, copying and printing, etc., justified quantitatively on the basis of previous experience, where relevant.

- 1.3.8 Consortium/Contractual Costs:** Financial support for individuals who are responsible for clinical trial and HRQOL committees or scientific services but are not employed by the Research Base awardee organization as well as per case management funding to institutional members is usually provided through consortium/contractual arrangements. Consortium/contractual costs for each participant requires a separate budget page, with appropriate justification. Indirect costs to consortium/contractual participants are included in the direct costs for the Research Base budget. NCORP Research Bases are encouraged to structure their organization in a manner which minimizes the burden of indirect costs on the overall Research Base budget.

1.4 Patient Care Costs

NCI will not support costs associated with routine patient care. Only in the most unusual circumstances would a Research Base clinical trial, HRQOL or cancer care delivery study require patient care activities beyond those considered appropriate for the care of cancer patients. In those circumstances, a Research Base may make a case for reimbursement of patient care costs associated with the particular research element as an administrative supplement. The justification should be presented by the Research Base Principal Investigator(s) to the NCORP Director with a specific request from each participating site based upon likely accrual to the specific study. This request would need to be approved/funded by NCI/DCP for the specific trial prior to activation of the study. Alternatively, the Research Base could seek other sources of funding for these costs (e.g., company collaborators, other NIH/NCI grant funding, charitable foundation funding).

In the case such funding was approved by NCI for a specific NCORP trial or study, it would be expected that the Research Base would provide this funding as "special per case management" funding to all institutions/sites (NCORP Community Sites, Minority/Underserved Community Sites and Research Base institutional members) that enrolled patients on the trial or study regardless of their Research Base affiliation or the Research Base credited with the accrual.

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1.5 Per Case Management Funding (Restricted)

The Research Base clinical trials budget must include “per case management” funding (if applicable) which must be restricted for this purpose. Per case management funding covers data collection and management and biospecimen collection for NCORP trials by member institutions/sites that are not funded as a NCORP Community Site or Minority/Underserved Community Site (hereinafter referred to as “institutional members”). This funding category should be estimated based on accrual projections for the Research Base institutional members to all NCORP trials if the accrual is expected to be credited to the applicant Research Base regardless of which Research Base is leading the trial. This funding amount is based on the amounts and funding algorithm specified in Part 4: Appendices – Section IV using the definitions provided below for the various categories of per case management funding.

The amounts for these funding categories as specified in Part 4: Appendices – Section IV reflect the total cost that should be provided to the Research Base institutional members. These amounts are set at the same level across NCORP regardless of the Research Base leading the trial and are applicable to both regular and pilot studies. It is recommended these amounts be used in creating the application budget.

The various categories of NCI/DCP supported per case management funding that should be included in a Research Base budget are described below.

- **Prevention:** Funding to cover data management and follow-up for subjects enrolled in prevention trials (chemoprevention, secondary prevention). Research Bases can request support for recruitment of non-cancer patients on a study-by-study basis.
- **Cancer control:** Funding to cover data management for patients enrolled in interventional or observational cancer control research studies aimed at reducing the incidence and co-morbidity of cancer and its treatment and enhancing the quality of life of those affected by cancer.
- **Screening/Post-treatment surveillance:** Funding to cover data management for patients enrolled in screening or post/treatment surveillance studies (e.g., imaging, biomarkers).
- **Treatment:** Funding to cover data management and follow-up for patients enrolled in a treatment trial who undergo the study intervention and/or randomization.

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- **Health-Related Quality of Life:** Funding to cover data management for patients enrolled in HRQOL studies embedded in treatment or imaging trials as secondary endpoints including those using patient-reported outcomes.
- **Advanced Imaging:** Funding to cover data management for subjects enrolled in advanced imaging studies
- **Molecular Screening:** Funding to cover data management costs for patients enrolled on a trial that require specific screening with informed consent as part of the trial (e.g., investigational molecular test of their tumor) and who do not subsequently undergo the study treatment/intervention and/or randomization because of the screening results. Per case management funding is provided for molecular screening or for one of the other categories listed below but never for both.
- **Biospecimen Collection Per Case Management Funding:** Funding to cover biospecimen collection and any associated biospecimen management costs for subjects enrolled on studies which require biospecimen collection and for subjects who agree to participate in optional biospecimen collections associated with trials. This category of funding would not be expected to be given in association with molecular screening per case funding except in unusual circumstances.

1.6 Consortium Arrangements

Consortium arrangements and all other contractual arrangements, including all mechanisms for providing per case management funding, must be formalized in writing in accordance with applicable NIH Grants Policy requirements, which are provided on the NIH website at:

http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch15.htm

. A statement that the applicant organization and the collaborating organization have established or are prepared to establish a formalized agreement that will ensure compliance with all pertinent federal regulations and policies must be included in the application.

1.7 Common Budget Outline & Projected Accrual by Institutional Member

The NCORP Research Base is encouraged, but not required, to submit a Common Budget Outline as described in Part 2 – Section II.A. of these Guidelines. A sample table for the Common Budget Outline is provided in Part 4 – Appendices - Section IX of these Guidelines. In addition to the Common Budget Outline, the Research Base is encouraged to also submit a breakdown of the accrual it anticipates from each of its institutional members (i.e., members that are not funded as a NCORP Community Site or Minority/Underserved Community Site) to all NCORP trials over the project period that was used as input to generate its budget

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request for per case management funding. A suggested format for a table to provide this information is presented in Part 4 – Appendices – Section X of these Guidelines.

2. Detailed Budget for Cancer Care Delivery Research for the Initial Budget Period

A budget and PHS 398/SF424 for cancer care delivery research should be provided.

2.1 Guidelines for Total Cost Cancer Care Delivery Research Budget Request

The total cost budget requested by the Research Base for cancer care delivery research in its application should include the following two elements:

- (1) Costs for the scientific and statistical leadership, data systems/informatics and management infrastructure necessary to develop, conduct and analyze cancer care delivery research studies (“infrastructure costs”)
- (2) Costs to cover study operations, statistical analysis, data management, quality control, study monitoring and auditing for studies led by the Research Base (“study-specific costs”)

No per case management costs for institutional members should be budgeted as only NCORP Community Sites and Minority/Underserved Community Sites will be funded to participate in cancer care delivery research studies.

Because cancer care delivery research was not a focus of activity under the previous CCOP Research Base awards, the expectation is that the balance of infrastructure costs versus study specific costs will evolve over the course of the initial award period for each Research Base. In the initial award year, the proposed budget for a Research Base is expected to be 100% infrastructure costs as likely no cancer care delivery research studies will have yet been developed and approved and it will take time to develop a scientific, statistical, data systems, informatics and management infrastructure to support this area of research. However, if a Research Base wishes to use part of their award to support study operations for a cancer care delivery research approved protocol, the portion of their budget devoted to this protocol will be restricted. Over the remaining award years, the percentage devoted to study specific costs is expected to increase, reaching a steady state of approximately 75% of the total Research Base budget for cancer care delivery research. The remaining 25% will continue to provide infrastructure support in terms of scientific and statistical leadership, data systems, informatics and management. Research bases are encouraged but not required to

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use the following example in preparing their budget submissions for subsequent award years:

- Year 2: 75% infrastructure, 25% study specific
- Year 3: 50% infrastructure, 50% study specific
- Year 4/5: 25% infrastructure, 75% study specific

The total cost Research Base budget is not expected to exceed \$700,000 per year and the funds for study-specific costs will be restricted for that purpose. As noted above, in the initial budget year the expectation is that the entire budget will be spent on developing a Research Base infrastructure to support cancer care delivery research. Applicants may request study specific funding in the initial year but should keep in mind that those funds will be restricted for study specific purposes. Beyond the initial funding period, the restricted funding for each Research Base will be dependent upon the number and costs of approved cancer care delivery research studies.

2.2 General Information

Since the organizational framework of each Research Base may be different, the budget for cancer care delivery research should be presented in logical, discrete units, with specific budgets for each unit. These units should include:

- infrastructure support for (a) scientific and statistical leadership, (b) data systems/informatics development and maintenance; and (c) overall management of the cancer care delivery research program
- Study specific funding for (a) study operations, (b) statistical analysis, (c) data management, (e) quality control, (e) study monitoring and (f) auditing for the menu of cancer care delivery research studies undertaken by the Research Base

Funding for cancer care delivery study-specific costs can also be covered by other sources of funding (e.g. R01/P01 grants, industry, nonprofit organizations and charitable support). If non-NCORP funds are obtained to support study-specific costs, the Research Base will be expected to solicit funds, as appropriate, to support participation in the study by NCORP Community Sites and Minority/Underserved Community Sites which should be provided by the Research Base as "special per case management" funding to all participating Sites.

2.3 Cost Categories

The applicant should provide a "level of effort" budget based on the budget categories described below which refer to those contained in the section of the PHS 398/SF424 pertaining to the

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detailed budget for initial budget period. **NOTE:** Specific job descriptions and qualifications for funded personnel (administrative as well as scientific) should be covered in this budget section and not repeated in the research plan narrative.

2.3.1 Personnel: A cancer care delivery research staffing plan for the Research Base, including position descriptions and qualifications should be provided. Precise justification for the amount of effort requested for each position is essential, including the following:

Infrastructure Costs include the following personnel costs:

- **Scientific Leadership:** Research costs include the time and effort of scientific and administrative committee chairs and/or co-chairs as well as study chairs and statistical leadership in developing the Research Base's strategy for cancer care delivery research as well as the development of study concepts and protocols, scientific monitoring of ongoing studies, analysis of results, and publication of research results in peer reviewed journals.
- **Data Systems/Informatics Infrastructure:** Research costs include the time and effort for information technology and informatics staff to establish and maintain data systems for cancer care delivery research, develop and maintain a working knowledge of site data systems and participate in developing standard NCORP wide data definitions and data collection tools and procedures.
- **NCORP-wide Repository Data:** Research costs include the time and effort involved in the collection, quality control and reporting of NCORP-wide repository data.
- **Site Training:** Research costs include the time and effort associated with training staff from NCORP Community Sites and Minority/Underserved Community Sites in collection of cancer care delivery research study data including the use of standard NCORP wide data definitions and data collection tools and procedures.
- **Creation and Coordination of Study Datasets for Data Sharing:** Personnel costs to support the creation and coordination of study data sets for data sharing in a timely manner after the primary results of cancer care delivery research studies are published.
- **Administration:** Research costs include the time and effort involved in the overall management/administration of Research Base activities that are specific to cancer care

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delivery research (e.g., project management effort).
General administrative costs for the Research Base are included in the clinical trials section of the budget (see Section 1 above)

Study-Specific Costs include the following personnel costs:

- **Study Operations:** Research costs include the time and effort of the Research Base staff in developing concepts and protocols, including associated regulatory and quality assurance activities, as well as management of trials and studies after activation (e.g., protocol amendment processing) and auditing.
- **Statistics:** Research costs include time and effort of the statistical staff in developing statistical designs and analysis plans for cancer care delivery research protocols as well as providing statistical analyses, interpretations, and conclusions with regard to study data and supporting required results reporting per federal regulation in www.clinicaltrials.gov as well as publication of those results in peer-reviewed journals.
- **Data Management:** Time and effort involved in the development of case report forms, central registration and enrollment of participants onto studies, collection and monitoring of primary data, collection and monitoring of secondary data, compliance with relevant data reporting and other regulatory requirements, and conducting and/or supporting quality assurance activities for cancer care delivery research studies.
- **Scientific Services:** Research costs include the time and effort involved in providing scientific services such as econometric review, psychometric review, etc. specific to the research goals of a Research Base study (i.e., not associated with conventional patient care or for educational purposes).

2.3.2 *Consultant Costs:* Reasonable consultant costs are allowed if the consultant is contributing in a substantial way to the conduct or development of the Research Base's cancer care delivery research strategy or to the conduct of cancer care delivery research studies, although clear and quantifiable justification is required. Costs include travel, per-diem and consultant fees, if applicable and within institutional policy.

2.3.3 *Equipment:* Only those equipment items that are required for Research Base activities relevant to cancer care

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delivery research should be included. Justification should include percent of time used for Research Base business as well as necessity for purchase. The amount of funds requested should be based on percent of use.

2.3.4 *Supplies:* Research costs for appropriate supplies with quantitative justifications based on actual use should be provided.

2.3.5 *Travel:* The importance of meetings to the achievement of the Research Base's overall cancer care delivery research strategy is obvious, as is the necessity to maintain careful control over the size of this budget item. The budget for travel must be itemized and justified. It should include the following:

- Travel by the Research Base's leadership and investigators on behalf of the Research Base to the NCI and other national organizations where the cancer care delivery research results of the Research Base are presented or where the Research Base's cancer care delivery research strategies are to be discussed;
- Travel for Research Base cancer care delivery scientific and administrative committee members to committee meetings held separately from major Research Base meetings;
- Travel for cancer care delivery protocol chairs and others who must perform quality assurance functions away from their home institution;
- Travel for persons on the Research Base staff who must attend the Research Base's meetings due to their involvement in cancer care delivery research activities (e.g., NCORP-wide data repository staff);
- Travel for the Research Base senior leadership for cancer care delivery research to attend NCORP Cancer Care Delivery Research Coordinating Committee meetings;
- Travel for the Research Base senior leadership to attend NCI/DCP Leadership Management Committee meetings for NCORP (if applicable);
- Travel associated with onsite audit program for cancer care delivery research;

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- Travel to NCORP Community Sites and Minority/Underserved Community Sites for training relative to cancer care delivery research; and
- A reasonable number of carefully justified trips for provisional Research Base members or other associated stakeholders (e.g., hospital administrative staff) to attend Research Base meetings to encourage participation and assure input from all relevant stakeholders in cancer care delivery research.

2.3.6 Alterations and Renovations: Costs for alterations and renovations are not allowable under NCORP.

2.3.7 Other Expenses: Research costs due to other expenses include those related to communication and information dissemination among participants in the NCORP Research Base cancer care delivery research program as well as with sites accruing participants to Research Base cancer care delivery research studies.

2.3.8 Consortium/Contractual Costs: Financial support for individuals who are responsible for cancer care delivery committees or scientific services but are not employed by the Research Base awardee organization is usually provided through consortium/contractual arrangements. Consortium/contractual costs for each participant requires a separate budget page, with appropriate justification. Indirect costs to consortium/contractual participants are included in the direct costs for the Research Base budget. NCORP Research Bases are encouraged to structure their organization in a manner which minimizes the burden of indirect costs on the overall Research Base budget.

2.4 Patient Care Costs

NCI will not support costs associated with routine patient care. Only in the most unusual circumstances would a Research Base cancer care delivery research study require interventions beyond those considered appropriate for the care of cancer patients. In those circumstances, a Research Base may make a case for reimbursement of patient care costs associated with the particular research element as an administrative supplement. The justification should be presented at the level of the Research Base Principal Investigator(s) to the NCORP Director and Associate Director with a specific request from each institution based upon likely accrual to the specific study. This request would need to be approved/funded by NCI/DCP for the specific trial prior to activation of the study. Alternatively, the Research Base could seek other sources of funding for these costs (e.g. other NIH/NCI grant funding, charitable foundation funding).

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2.5 Consortium Arrangements

Consortium arrangements and all other contractual arrangements must be formalized in writing in accordance with applicable NIH Grants Policy requirements, which are provided on the NIH website at:

http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch15.htm

. A statement that the applicant organization and the collaborating organization have established or are prepared to establish a formalized agreement that will ensure compliance with all pertinent federal regulations and policies must be included in the application.

3. Research Plan

In the "Research Plan" section of the NCORP Research Base application, a Specific Aims page should be provided as well as separate PHS 398 Research Strategy Sections for the 6 sub-sections listed below within the corresponding specified page limits (and the Table of Contents for the Research Plan section of the application should be modified accordingly). The 6 sub-sections are listed below.

- A. Research Base Overview and Leadership - 12 pages
- B. Cancer Prevention, Control and Screening Trial Development Program - 12 pages
- C. Statistical Analysis/Data Management for Cancer Prevention, Control and Screening Trials - 12 pages
- D. Cancer Care Delivery Research Program - 12 pages
- E. Operational Management - 12 pages
- F. Collaboration and NCORP Collective Management - 6 pages

Other sections of the PHS 398 Research Plan (398 application instructions Part I, Section 5.5), such as the sections for Letters of Support (e.g., Letter of Support from the institution or organization sponsoring the NCORP Research Base) and Multiple Program Director/Principal Investigator (PD/PI) Leadership Plan, remain unmodified and must be completed following standard instructions.

Table of Contents for the NCORP Research Base application

Specific Aims (including Impact Statement) - 1 page

Research Strategy Section for the NCORP Research Base Application

This section must consist of the sub-sections A. –F. described below.

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3.1 Sub-section A. Research Base Overview and Leadership (*up to 12 pages*)

In this sub-section, applicants are expected to provide a general overview of the proposed Research Base and describe its features and operations. Include a diagram illustrating the organizational structure and describe how the scientific, operational, statistical and data management components will interact. Outline how the affiliated NCORP Community Sites, NCORP Minority/Underserved Community Sites and other institutional members will be involved (e.g., committee memberships, study chair positions, training programs, authorship on publications, etc.). Describe approaches for facilitating communication and coordination among affiliated NCORP Sites and other members and how the cancer prevention, control, and screening clinical trials program will be coordinated with the cancer care delivery research program.

Describe qualifications and experience in clinical trials design and conduct of cancer care delivery of a designated PD/PI (or multiple PDs/PIs if this option is used) as well as the individuals designated to coordinate cancer prevention, control, and screening/post-treatment surveillance clinical trials and cancer care delivery research, respectively, if different from the PD/PI/PD. Provide information on key leadership staffing including statistical leadership and senior members of applicant's research team who will lead its scientific committees regarding the impact of their publications on their field of research expertise and details about their community-based research experience. Describe the scientific expertise of members of the applicant's multi-disciplinary oncology research team and other professionals such as epidemiologists, statisticians, health economists, health services, behavioral, and disparities researchers who will be involved in the activities of the Research Base.

NOTE: Supplementary information on the applicant's scientific and statistical leadership may be summarized in the Key Leadership Staffing table as described in the Resources Section above.

3.2 Sub-section B. *Cancer Prevention, Control and Screening/Post-treatment Surveillance Trial Development Program (up to 12 pages)*

In this sub-section, applicants are expected to address the following aspects.

Research Priorities. Define the overall priorities for development of cancer prevention, control, and screening/post-treatment surveillance clinical trials, including health-related quality-of-life studies embedded in treatment and/or imaging clinical trials (if applicable). Identify disease areas, patient populations (including high risk cohorts and patients predisposed to treatment toxicities), disease-related symptoms, treatment-related toxicities

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and disparities questions that will be pursued. Research Bases are not required to conduct research in all areas within NCORP clinical trials (cancer prevention, control, screening, and health-related quality of life). Applicants should describe how the overall chosen areas of research priorities reflect the scientific interests and expertise of their research team.

Capabilities and Experience. Summarize the capabilities and experience of the applicant team in successfully developing, organizing, coordinating, and analyzing multi-institutional cancer prevention, control, and screening clinical trials and health-related quality-of-life studies embedded in treatment and/or imaging clinical trials (if applicable), especially in the context of working with community organizations. Outline the most important achievements in these areas over the past 5 years and also list ongoing clinical trials. Applicants should demonstrate their ability to design clinical trials that are feasible to conduct in the community setting and achieve high levels of participation by community physicians and their patient populations including minority/underserved participants.

NOTE: Information on the applicant's achievements over the prior 5 years and ongoing trials may be summarized in tables as described in the Resources Section above.

Research Directions. Describe an integrated and cohesive research agenda identifying the applicant's chosen area of focus and highest priority future research directions as well as any clinical trials currently in development. Describe how the proposed research agenda will emphasize clinical trials addressing mechanisms of cancer symptoms and treatment toxicities, observational or longitudinal studies to understand the natural history of cancer symptoms and treatment-related toxicities, molecularly-targeted agents to understand toxicities, post-treatment surveillance, under-diagnosis and over-diagnosis, and management of precancerous lesions. Observational and longitudinal studies may be used in symptom and toxicity management when appropriate to inform and lead to intervention clinical trials. Describe the process for including biospecimen collection in clinical trial design when appropriate and opportunities for developing clinical trials based on the results and experiences from previous clinical trials. Describe the process for ensuring that the clinical trial aims, hypotheses, and designs will be pertinent to community physicians and their patient populations, are feasible to implement in the community, and provide opportunities to evaluate differential outcomes in minority/underserved populations. It is expected that an overall summary of the research agenda will be provided and not detailed descriptions of proposed studies.

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NOTE: Information on clinical trial protocols and concepts currently in development or under review may be summarized in a table as described in the Resources Section above.

Scientific Committee(s). Define the proposed scientific committee(s) and their role in the development of the research agenda. Outline the composition and function of each committee as well as the organizational relationship between the various committees, if any. For committees that are not yet formed, outline the purpose, type of expertise sought, and identify potential members of such committees. Describe succession plans and term limits for committee leadership.

New & Junior Investigator Leadership Mentoring/Training. Describe a mentorship/training program for new and junior investigators that provides opportunities for leadership of clinical trials (e.g., developing clinical trial concepts, serving as study chairs, and participation in scientific committees). Outline plans for the involvement of senior members of scientific committees in the mentorship/training program.

Community Site Engagement. Describe plans for engaging NCORP Community Sites and Minority/Underserved Community Sites in the design and conduct of cancer, prevention, control, and screening/post-treatment surveillance clinical trials as well as the mentoring of sites in the capabilities necessary to conduct such clinical trials. Describe plans to foster opportunities for participation on scientific and community oncology committees. Describe the processes for and experience with educating community sites on protocol specific requirements.

Accrual. Provide information on total accrual to cancer prevention, control, and screening clinical trials led by the applicant over the past 5 years. Provide long-term plans for facilitating the recruitment and retention of participants or patients to cancer prevention, control, and screening/post-treatment surveillance clinical trials led by the applicant, including programs or plans for the recruitment and retention of minorities and other underserved populations. In these plans, describe how the Research Base will work with the NCORP Community Sites and Minority/Underserved Community Sites that are or will be affiliated with the applicant, as well as other affiliated members, to facilitate recruitment and retention. In addition, describe the processes for assessing accrual feasibility for proposed clinical trials and for monitoring accrual post-activation and implementing appropriate corrective action plans if accrual is lagging.

NOTE: Information on the accrual to cancer, prevention, control and screening/post-treatment surveillance trials led by the applicant over the past 5 years should be summarized in tables as described in the Resources Section above.

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3.3 Sub-Section C. Statistical Analysis/Data Management for Cancer Prevention, Control and Screening/Post-treatment Surveillance Trials (up to 12 pages)

In this sub-section, applicants are expected to address the following aspects.

Statistical Analysis. Describe the general approach to statistical design and analysis for multi-institutional cancer prevention, control, and screening clinical trials, including observational and longitudinal studies as applicable. This should include guidelines for interim monitoring and general procedures for sample size estimation for parent and sub-studies, choice of testing and estimation procedures, and handling of missing data. Describe how the statistical team provides leadership in clinical trial design and analysis as well as examples of robust statistical clinical trial designs. Describe how the statistical team participates in Research Base scientific committees and collaborates with study chairs and study teams in clinical trial design and ensuring that final study analyses are performed in a manner to provide timely publication of study and sub-study results and results reporting per NCI and federal regulations. Describe approaches for cross-Research Base collaboration in sharing statistical methodologies, standards, and best practices. The qualifications, experience, and duties of proposed statistical personnel should be described.

NOTE: Formal policies and standard operating procedures for statistical analysis (e.g., guidelines for interim monitoring) should be provided in the Resource section of the application.

Data Management. The applicant should provide a description of data management practices including the flow and review of clinical data following submission from individual institutions/sites. The applicant should describe the data management systems employed, facilities and equipment available, and the information technology support provided for central storage, security, analysis and retrieval of clinical trial data. Descriptions of training for study chairs, site investigators, and site support staff related to data management should be provided. The qualifications, experience, and duties of proposed data management personnel should be described.

3.4 Sub-Section D. Cancer Care Delivery Research Program (up to 12 pages)

In this sub-section, applicants are expected to address the following aspects.

Research Priorities. Define the overall research priorities for the development of multi-institutional, community-based cancer care delivery research, highlighting the particular aspects of care

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delivery and the types of study designs and research methodologies that will be pursued. The applicant should also outline approaches for incorporating health disparities research questions into studies and designing studies specific to hospitals, clinics, and other cancer care settings that serve predominantly minority and/or underserved populations. The envisioned studies may be observational or interventional in design. Observational studies may address the effect of alternative care models on patient outcomes (e.g., patterns of care or service utilization; organizational policies; health behavioral improvement programs; organizational structures such as integrated healthcare systems versus freestanding hospitals). Interventional studies may address implementation of new technologies (e.g., decision-making tools to support genomically-informed diagnostic test or therapies), new approaches for team-based care such as multi-modality therapy planning and delivery, patient navigation and other care processes, and/or incorporation of new types of information (e.g., patient reported information) into clinical decision-making, etc. The applicant should also describe how they will collaborate with other Research Bases to build a coordinated cancer care delivery research program within NCORP and how the cancer care delivery research priorities reflect the scientific interests and expertise of the applicant team. The applicant should also describe the proposed capacity building activities to be undertaken at the beginning of the award (e.g., data systems development, simulation, and training activities).

Capabilities and Experience. Describe the team of cancer care delivery research investigators assembled by the applicant and their capabilities and experience, if any, in developing, organizing, coordinating, and analyzing multi-institutional observational and interventional cancer care delivery research, including experience working with community organizations in conducting such studies. Highlight experience, if any, with conducting studies that incorporate disparities research questions and address minority/underserved populations. Describe how these investigators will work as a cohesive research team, both within the applicant's Research Base and with other NCORP Research Bases, to develop and conduct cancer care delivery research. Describe plans for recruiting additional cancer care delivery research investigators unaffiliated with the applicant, if applicable. Outline any past cancer care delivery research accomplishments by the applicant team and describe any ongoing cancer care delivery research as well as any studies currently in development.

NOTE: Information on the applicant team's past accomplishments, if any, in cancer care delivery research and any ongoing studies may be summarized in tables as described in the Resources Section above.

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Scientific Committees. Define the proposed cancer care delivery research scientific committee(s) and describe their role in development of the Research Base's research agenda. Outline the composition, function, and proposed membership of each committee as well as the organizational relationship between the various committees, if any.

Statistical Analysis/Informatics Support. The applicant should describe the general approach and methodologies for statistical design and analysis of the cancer care delivery research envisioned by their research strategy. This description should include procedures for sample size estimation, survey design, handling missing data, multi-level methods for analysis of financial/service utilization data and incorporation of multi-level provider/patient, organization, and system data into study designs. Particular attention should be paid to use of standard statistical methods for multi-site observational and interventional health services and behavioral research studies. Describe the approach for developing a working knowledge of the strengths and weaknesses of the data structures of inpatient/ambulatory data systems (e.g., registries, electronic medical records [EMRs], financial and administrative databases) at NCORP Community Sites and Minority/Underserved Community Sites. The qualifications, experience, and duties of proposed statistical personnel should be described.

NOTE: Formal policies and standard operating procedures for statistical analysis (e.g., guidelines for interim monitoring, survey response rate estimation) should be provided in the Resource section of the application.

Data Management. The applicant should provide a description of proposed methods and approaches for the following:

- Developing a working knowledge of the specific inpatient/ambulatory data systems (e.g., registries, EMRs, financial and administrative databases) in place at the individual NCORP component sites participating in cancer care delivery research
- Managing the flow and review of registry, EMR, financial, service utilization and administrative data provided by NCORP Community Sites and Minority/Underserved Community Sites
- Working with other Research Bases to develop and maintain common NCORP-wide repositories of community site data (e.g., cancer registry, processes of care, practice guidelines, organizational policies, provider, facility, organizational and community characteristics)
- Data management systems that will be employed, facilities and equipment available and the information technology support provided for central storage, security, analysis and retrieval of

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- registry, EMR, financial, service utilization and administrative data
- Training for study chairs, site investigators and site support staff related to data management.

The qualifications, experience, and duties of proposed data management personnel should be described.

New & Junior Investigator Leadership Mentoring/Training.

Describe the mentorship/training program for new and junior investigators that provides opportunities for leadership of cancer care delivery research (e.g., developing study concepts, serving as study chairs and participation in scientific committees). Outline plans for the involvement of senior members of scientific committees in the mentorship/training program.

Community Site Engagement. Describe plans for engaging NCORP Community Sites and Minority/Underserved Community Sites in the design and conduct of cancer care delivery research as well as the mentoring of sites in the capabilities necessary to conduct such studies. These plans should involve not only oncologists but also primary care and other providers, other professionals (e.g., administrators, care coordinators, genetic counselors) and staff responsible for managing databases (e.g., cancer registries, financial systems, service utilization systems) relevant to cancer care delivery research. These plans should foster opportunities for participation of these individuals on scientific and community oncology committees.

NCORP Cancer Care Delivery Coordination Committee.

Representatives from all Research Bases will be expected to form a joint Committee to develop an overall agenda for cancer care delivery research under NCORP. For details see [Section VI.2. Cooperative Agreement Terms and Conditions of the Award](#). Applicants must plan to participate in the activities of this Committee.

3.5 Sub-Section E. Operational Management (*up to 12 pages*)

In this sub-section, address the operational aspects of the proposed Research Base including its governance, policies and procedures. All these elements are expected to be designed to optimize the applicant's ability to develop, activate, and conduct clinical trials and cancer care delivery research in a timely manner. Specifically, address the following aspects.

Governance. Define the roles and responsibilities of the PD(s)/PI(s), including responsibilities for human subjects in research. If applicable, outline in this sub-section a rationale and

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the general benefits of choosing a multiple PD(s)/PI(s) approach.

NOTE: Applicants designating multiple PD(s)/PI(s) must also complete the dedicated Section of PHS 398 Research Plan "Multiple PD(S)/PI(S) Leadership Plan." Delineate the roles of other key members of the leadership team in terms of scientific, administrative, and/or technical responsibilities, as appropriate, such as any Director of Operations and/or Administrator positions and any Executive/Advisory Committee(s). Outline communication plans, processes for making decisions on scientific directions, and procedures for resolving conflicts. Include succession plans for key leadership positions and policies governing term limits. In addition, describe the policies governing the applicant's financial management as well as affiliation of NCORP Community Sites and Minority/Underserved Community Sites.

Study Operations. Outline operational practices for clinical trials and cancer care delivery research including those for protocol development, development of data collection and extraction tools, regulatory activities, site support, and study specific protocol training for study chairs, site investigators and site support staff. Describe procedures for tracking the timelines for protocol development and activation and complying with any internal or NCI-mandated timelines for study activation.

Study Monitoring/Quality Control. Outline procedures for study monitoring, data quality control and accuracy verification, including auditing. Describe the methods used for active study monitoring, including procedures for accrual and biospecimen collection tracking, assessing subject eligibility and evaluability, ensuring timely medical review and assessment of patient data, monitoring of data quality and timeliness, and resolving issues. Summarize quality and timeliness guidelines for participating sites and guidelines for reporting to the sites on their performance relative to those guidelines. Provide a brief narrative on clinical trial data quality and timeliness for the past 5 years. Summarize the results of clinical trial audits for affiliated CCOP, MB-CCOP, and other institutional members for cancer prevention, control, and screening clinical trials led by the Research Base over the last 5 years.

NOTE: Comprehensive and detailed information on the applicant's clinical trial data quality and timeliness and summary audit results for the past 5 years may be summarized in tables as described in the Resources Section above.

Site Performance Evaluation. Criteria for affiliation of NCORP Community Sites and Minority/Underserved Community Sites with the Research Base should be described as well as policies and procedures for evaluating performance against those criteria. Policies and procedures for evaluating performance of other

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Research Base member/affiliate institutions participating in cancer prevention, control and screening clinical trials must be described as well. Describe processes for implementing corrective actions for observed deficiencies.

Standard Tools. Describe utilization of the available, NCI-supported standard tools and services for the conduct of clinical trials including the Common Data Management System (CDMS), Common Data Elements (CDEs) from the Cancer Data Standards Registry and Repository (caDSR), the Regulatory Support System (RSS), the Oncology Patient Enrollment Network (OPEN), the Clinical Data Update Systems (CDUS/CDS), the Expedited Adverse Event Reporting System (AdEERS) and the Common Terminology Criteria for Adverse Events (CTCAE).

Compliance. Briefly describe the applicant's policies for assuring compliance with NCI,NIH, HHS and other Federal regulations regarding the following:

- Study Monitoring
- Data and Safety Monitoring
- Onsite Auditing
- Ensuring Security and Confidentiality of Participant and Other Sensitive Data
- Use of Standard Informed Consent Template for clinical trials
- Conflict of Interest

Present a plan and demonstrate its ability to adhere to regulations regarding trial registration in the NCI Clinical Trials Reporting Program and in the U.S. National Library of Medicine (NLM) (www.clinicaltrials.gov) along with results reporting, as applicable.

Describe its plan to ensure that results from clinical trials and cancer care delivery research will be published in a timely manner. The applicants should address their compliance with the data sharing policy and making biospecimens from clinical trials accessible to qualified researchers for further research or explain why sharing is not possible. Include the procedures that will be used, a timeline for making the data and specimens available, and how the rights and confidentiality of participants are protected. Information on the use of biospecimens from the applicant's NCI-supported cancer prevention, control, and screening clinical trials over the last 5 years should be provided.

NOTE: Detailed information on the applicant's formal policies and standard operating procedures for affiliations of NCORP Community Sites and Minority/Underserved Sites, standard tools, compliance, and use of biospecimens from NCI-supported cancer prevention, control, and screening trials over the past 5 years, if applicable,

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may be summarized in tables as described in the Resources Sections of the application.

3.6 Sub-section F. Collaboration and NCORP Collective Management (up to 6 pages)

In this sub-section, address the following aspects.

Research Collaborations.

- Describe current and potential collaborative interactions of the applicant team with investigators from other NCI-sponsored programs (e.g., current CCOP Research Bases, the Cancer Research Network, NCI-designated Cancer Centers, the Early Detection Research Network, Partnerships to Advance Cancer Health Equity, Community Networks Program Centers, Specialized Programs of Research Excellence, R01/P01 investigators)
- Describe relevant current and potential collaborative interactions with non-NCI-supported research programs, minority professional societies, advocacy groups, nonprofit organizations, etc.

NCORP Collective Management. The NCORP Research Base team will be expected to participate in the collective management of NCORP and must plan according. Activities in the collective management will include but not be limited to the following: meetings of NCI Scientific Steering Committees and associated Task Forces, Planning Committees for scientific Steering Committees, the NCI adult and pediatric Central Institutional Review Boards and/or similar collaborative activities involving other clinical trial networks.

3.7 Protection of Human Subjects

Applicants should consult the PHS 398/SF424 regarding general instructions on what types of information should be included in the application regarding human subjects' research, including the protection of human subjects. The NCORP Research Base application must address the inclusion of women and minorities and inclusion of children in its clinical research as required per NIH/NCI Policy.

Information on the targeted/planned enrollment table for minorities and members of both genders (as well as children, if applicable), should be based on accrual summarized across all diseases for the planned project period in the competing new application (Type 1), not on a study or disease-specific basis.

Information on the policies for inclusion of women and minorities is available at:

http://grants.nih.gov/grants/funding/women_min/women_min.htm

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<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>
http://grants.nih.gov/grants/funding/women_min/guidelines_ameended_10_2001.htm

Information on the policies for inclusion of children is available at:

<http://grants.nih.gov/grants/funding/children/children.htm>
<http://www.nih.gov/grants/guide/notice-files/not98-024.html>

NIH policy requires that children (i.e., individuals under 21 years of age) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them as described at:

<http://grants.nih.gov/grants/funding/children/children.htm>. For cancer clinical research, NCORP Research Bases conducting research in adult cancers can provide a rationale for not including children because the majority of children with cancer in the United States are already accessed by a Research Base devoted to pediatric cancer research, so that requiring inclusion of children in the proposed adult study would be both difficult and unnecessary (since the research question is already being addressed in children by the pediatric Research Base) as well as potentially counterproductive since fewer children would be available for the pediatric Research Base study if other studies were required to recruit and include children.

3.8 Resource Sharing Plans

Applicants are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS) as provided in the PHS 398 Application Guide with the following modifications:

- Generally, Resource Sharing Plans (Data Sharing Plan, [Sharing Model Organisms](#) if applicable, and [Genome Wide Association Studies \(GWAS\)](#) are expected in this application.
- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan. An example of a Data Sharing Plan for NCORP Research Base for NCORP is provided in Part 4 – Appendices – Section VII in these Guidelines.

The Data Sharing Plan and other resource plans (or rationale for not providing sharing certain resources) should be provided in the research application; however, prior to funding of an award, all resource sharing plans/policies will also need to be reviewed and approved by NCI/DCP program staff prior to funding any award in order to ensure that the plans/policies are in compliance with NCI/NIH regulations and the Terms of the Award for the applicable key component of NCORP.

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4. Appendix Material & Post Submission Materials

Information on the Appendix material that should be provided in the NCORP Research Base application, along with information on the timing of submission of this material and the format in which it should be provided is described in Part 2 – Section I.D. of these Guidelines.

In addition to the information that can be included in the Appendix material described in that section, copies of up to 3 protocol documents described or referenced in the narrative of Sub-section B (Cancer Prevention, Control and Screening Trial Development Program) of the research plan for the proposed NCORP Research Base illustrating the applicant's overall research directions may be submitted in the Appendix. The applicant may not submit copies of all protocols being conducted or in development by the applicant in the Appendix.

Information on post submission materials that may be provided for the NCORP Research Base application is described in Part 2 – Section I.F of these Guidelines.

5. Just-in-Time Information

The following material must be submitted prior to the award of the Cooperative Agreement for the NCORP Research Base.

5.1 Other Support for Key Personnel

NCI program staff will contact all applicants to be funded to request "Other Support" for Key Personnel, including consortium/contract personnel. "Other Support" includes all financial resources, whether federal, non-federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, Cooperative Agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included. Percent effort should be specified as well as any support that is pending. Information on other support assists the awarding NCI staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating such overlap are to ensure that: (1) sufficient and appropriate levels of effort are committed to the project, (2) there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort, and (3) only funds necessary to the conduct of the approved project are included in the award.

5.2 Training on Human Subjects Protection for Key Personnel

As part of Just-In-Time information, the NCORP Research Base should also submit a roster of Key Personnel and indicate the type of training program on human subjects protection completed by each person listed. The NIH policy on Human Subjects Protection is available at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

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5.3 Onsite Auditing Activities

The NCI-CTMB Guidelines for Monitoring of Clinical Trials for Cooperative Groups, CCOP Research Bases, and the Cancer Trials Support Unit (CTSU) require all Participating Sites to be audited at least once every 36 months. In order for the NCI to review the NCORP Research Base compliance with this requirement, the NCORP Research Base should conduct a comprehensive review of its membership and provide **updated** auditing information for all Participating Sites and affiliates to the NCI/DCP Senior Program Specialist two months prior to the anticipated award. This information should be provided in tabular format as part of Just-In-Time Information and should include the following: (1) date of affiliation with or termination from the NCORP Research Base; (2) accrual for the immediate preceding 36 months broken down by year; (3) the projected accrual for the upcoming year; (4) the date of the institution's last audit; and (5) the date or projected month/year of the next proposed audit. See Part 4 – Appendices – Section II.A.9.

5.4 Provision of Funds to Member Institution/Sites for Per Patient Data Management

If the NCORP Research Base provides funds to member institutions/sites for accruals (non-NCORP Community and Minority/Underserved Community Sites and their components) via per-accrual reimbursement mechanisms (e.g., purchased service agreements or subcontracts), the following information must be provided as Just-In-Time information by a scheduled date to be specified by NCI/DCP:

- For the upcoming budget period: (1) the estimated number of per patient accruals by category (screening, intervention, and biospecimen accruals) by major disease area and within each disease area by trial led by the Research Base; (2) the estimated number of per patient accruals by category (screening, intervention, and biospecimen accruals) by major disease area for trials that will not be led by the Research Base; and (3) the estimated total costs (direct and indirect) that the Research Base anticipates providing to member institutions/sites, with corresponding NCI institution codes, via this award.

5.5 Data and Safety Monitoring Boards/Plans and Updates

The NCORP Research Base should have a Data and Safety and Monitoring Board (Data Monitoring Committee) policy for randomized phase 2 and phase 3 NCORP trials that complies with the "NCI NCORP Program Data and Safety Monitoring Board Policy" as provided in Part 4 – Appendices – Section VIII of these Guidelines. In addition, the NCORP Research Base must have Data and Safety Monitoring plans for all other NCORP Research Base studies that comply with the NIH policy for data and safety monitoring, posted on the NIH website at: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>, with

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additional description at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>.

These policies/plans should be provided in the research application; however, prior to funding of an award, all Data and Safety Monitoring Board (Data Monitoring Committee) policies/plans (and any updates to these policies/plans) will also need to be reviewed and approved by NCI/DCP program staff prior to funding of an award to ensure that they are in compliance with NCI/NIH regulations.

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C. NCORP Community Site Application

Specific instructions are provided on the following pages for the NCORP Community Site application. In general, except where noted below, all NCORP Community Site applications should conform to the instructions in the PHS 398/SF424.

Total Budget for an NCORP Community Site: The budget of a NCORP Community Site is divided into two parts: (1) a clinical trials budget which includes costs for data collection and management and biospecimen collection for subjects enrolled in cancer treatment, advanced imaging, prevention, control and screening/post-treatment surveillance clinical trials as well as health-related quality of life (HRQOL) studies embedded within treatment and imaging trials and (2) a cancer care delivery research budget for participation in cancer care delivery research studies. A separate PHS 398/SF424 is required for each part.

1. Detailed Clinical Trials Budget for the Initial Budget Period

A separate budget and PHS398/SF424 for clinical trials should be provided.

1.1 Estimation of Total Cost Clinical Trials Budget Request

The total cost budget requested by the NCORP Community Site in its application should be based on the two elements described below, using guidelines provided in Part 4 – Appendices – Section IV of these Guidelines:

- i. Infrastructure funding for the Community Site to establish and maintain a clinical research capacity
- ii. Variable “per case management” funding based on an algorithm that estimates the variable costs for data collection and management and biospecimen collection based on the trailing three year average annual credits received by the NCORP Community Site for subjects enrolled by all its component sites in cancer treatment, advanced imaging, prevention, control and screening/post-treatment surveillance clinical trials as well as health-related quality of life (HRQOL) studies embedded within treatment and imaging trials and a fixed cost multiplier determined by the historical level of accrual for the NCORP Community Site

Community Sites that received more than 200 credits annually during the past three years may be eligible to use the “high performance” per case management funding dollar amount (i.e., \$4000). Past experience indicates high accruing sites may need additional resources to compensate for the larger number of patients who must be followed over multiple future years while Community Sites that consistently received less than 200 credits during the past three years may only qualify for the “basic” per case management funding amount (i.e., \$2500). All applicants

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must provide justification for the amount requested based on actual costs to be incurred by the organization.

1.2 Cost Categories

Once the NCORP Community Site applicant has determined the amount of its total cost budget request for clinical trials using the guidelines specified in Part 4 – Appendices – Section IV of these Guidelines, the applicant should provide a “level of effort” budget based on the budget categories described below. These categories refer to those contained in the section of the PHS 398/SF424 pertaining to the detailed budget for the initial budget period.

1.2.1 **Personnel:** A clinical trials staffing plan for the NCORP Community Site, including position descriptions and qualifications should be provided. **NOTE:** Specific job descriptions and qualifications for funded personnel (administrative as well as scientific) should be covered in this budget section and not repeated in the research plan narrative. Precise justification for the amount of effort requested for each is essential, including the following:

- **Investigator Efforts:** Research costs include the time and effort involved in overseeing NCORP clinical trial research activities of the Community Site and its participating components.

NOTE: Funding for positions within the senior leadership of a NCORP Research Base (i.e., Executive Medical Officer, Executive Committee positions, Scientific and Administrative Committee Chair/Co-Chair positions, Study Chair positions) should be funded by the Research Base award.

- **Data management:** Research costs include the time and effort involved in accurate collection and submission of clinical trial and HRQOL study data.
- **Scientific Services:** Research costs include the time and effort related to providing specific services such as pathology and radiology review for clinical trials and HRQOL studies.
- **Administration:** Research costs include the time and effort involved in coordinating clinical trial research activities at the NCORP Community Site including regulatory activities, implementation of quality assurance and study monitoring procedures and participation in NCORP onsite audit program.

1.2.2 **Consultant Costs:** Consultant costs are not usually appropriate in this award, so requests should be

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justified in detail. These costs include travel, per-diem, and consultant fees, if applicable and within institutional policy.

- 1.2.3 *Supplies, Equipment, and Other Costs:* Research costs for appropriate supplies, with quantitative justifications based on actual use, should be provided. Significant equipment costs are unusual in this award, and such costs must be justified in detail. The amount of funds requested for equipment should be based on the percent of usage. Research costs due to other expenses include those associated with communication with the various NCORP Research Base and/or Network Groups' offices, the costs of compiling and mailing data and the costs of mailing or handling patient-related specimens, forms, and materials (e.g., slides, X-ray films).
- 1.2.4 *Travel:* Travel for a reasonable number of the NCORP component sites' participating investigators, data managers, and nurses to attend the regular meetings of the various NCORP Research Bases and/or Network Groups should be included in the budget. **NOTE:** Attendance of investigators at meetings on behalf of the NCORP Research Base and/or Network Groups, or at special (i.e., non-routine) meetings of committees of the various NCORP Research Bases and/or Network Groups, should generally be funded through the respective NCORP Research Base and/or Network Group, rather than through this award.
- 1.2.5 *Patient care costs:* NCI will not support costs associated with routine patient care.
- 1.2.6 *Consortium/Contractual costs:* Separate budget pages with detailed justification of all requested items should be submitted for each consortium agreement and applicable indirect costs should be included.

1.3 Rationale for Budget Policy

NCORP Community Sites considered "high performance" sites may receive a higher rate for per case data management funding because of the burden of the large number of patients accrued.

1.4 Consortium/ Contractual Arrangements

Consortium arrangements and all other contractual arrangements, including mechanisms for reimbursement of component sites for administration management/data management for patient accrual, must be formalized in writing in

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accordance with applicable NIH Grants Policy requirements available at: http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch15.htm. A statement that the applicant organization and the collaborating organization have established or are prepared to establish a formalized agreement that will ensure compliance with all pertinent NCI, NIH, DHHS, and federal regulations and policies must be included in the application.

2. Detailed Budget for Cancer Care Delivery Research for the Initial Budget Period

A separate budget and PHS398/SF424 for cancer care delivery research should be provided.

NOTE: The applicant must identify at least one component site that will participate in cancer care delivery research studies. The component site(s) must be able to implement on-site cancer care delivery research studies, provide organizational data (e.g., financial, service utilization, processes of care, organizational policy) in support of cancer care delivery research studies, and mentor other components in their NCORP awardee network in cancer care delivery research. These capabilities can all be provided by a single component site or by more than one component site. Alternatively, the various capabilities may be distributed over two or more different component sites.

2.1 Estimation of Total Cost Cancer Care Delivery Research Budget Request

The total cost budget requested by the NCORP Community Site for cancer care delivery research in its application should include the following elements for each component site designated for participation in cancer care delivery research:

1. Costs for overall scientific and management leadership and coordination for research program
2. Costs for study coordinator and data system staff to conduct studies

Because cancer care delivery research was not a focus of activity under the previous CCOP awards, the expectation is that the majority of the Community Site budget in the initial award year will be for evaluating and enhancing the informatics and data collection/reporting capabilities with regard to cancer care delivery research at the designated component sites and in training their research and data systems staff in this area of research. In subsequent award years, the funding is expected to move primarily toward supporting participation in specific studies.

At a minimum, Community Site funding for cancer care delivery research activities is expected to support approximately 5% time

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for a lead investigator who provides scientific oversight of the cancer care delivery research program and approximately one staff FTE to support data management and study coordination for at least one component site designated for participation in cancer care delivery research. Community Sites with (1) one or more component sites with demonstrated experience and capacity in cancer care delivery research; (2) one or more component sites with additional data collection capabilities (e.g., linking registry, medical records and administrative data); and/or (3) more than one component site with the interest and capacity to conduct cancer care delivery research will be candidates for increased levels of funding. The total cost budget request from Community Sites with additional component sites and/or enhanced capacity may qualify for higher levels of funding. The budget justification should clearly delineate the proposed use of funds requested.

2.2 Cost Categories

The applicant should provide a "level of effort" budget based on the guidance above and the budget categories described below. These categories refer to those contained in the section of the PHS 398/SF424 pertaining to the detailed budget for the initial budget period.

2.2.1 *Personnel:* A cancer care delivery research staffing plan for the component site(s) designated to participate in cancer care delivery research, including position descriptions and qualifications should be provided. **NOTE:** Specific job descriptions and qualifications for funded personnel should be covered in this budget section and not repeated in the research plan narrative. Precise justification for the amount of effort requested for each is essential, including the following:

- **Investigator Efforts:** Research costs include the time and effort involved in overseeing NCORP cancer care delivery research activities of the participating component site(s).

NOTE: Funding for positions within the senior leadership of a NCORP Research Base for cancer care delivery research (i.e., Scientific and Administrative Committee Chair/Co-Chair positions, Study Chair positions) should be funded by the Research Base award.

- **Data management:** Research costs include the time and effort involved in accurate collection and submission of cancer care delivery research study data.
- **Scientific Services:** Research costs include the time and effort related to providing specific services such as

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informatics support or mentoring investigators of other component sites within their NCORP Community Site network in the conduct of cancer care delivery research.

- **Administration:** Research costs include the time and effort involved in coordinating cancer care delivery research activities at the the participating component site(s), including regulatory activities, implementation of quality assurance and study monitoring procedures and participation in NCORP onsite audit programs.
- **NCORP-wide Repository Data:** Research costs include the time and effort involved in the collection and reporting of NCORP-wide repository data to affiliated Research Bases.

2.2.2 *Consultant Costs:* Consultant costs are not usually appropriate in this award, so requests should be justified in detail. These costs include travel, per-diem, and consultant fees, if applicable and within institutional policy.

2.2.3 *Supplies, Equipment, and Other Costs:* Research costs for appropriate supplies, with quantitative justifications based on actual use, should be provided. Significant equipment costs are unusual in this award, and such costs must be justified in detail. The amount of funds requested for equipment should be based on the percent of usage. Research costs due to other expenses include those associated with communication with the various NCORP Research Bases' offices, the costs of compiling and mailing data and the costs of mailing or handling patient-related specimens, forms, and materials (e.g., registry records, medical record abstraction forms).

2.2.4 *Travel:* Travel for the cancer care delivery research lead investigator and study coordination or data management staff from the participating component site(s) to attend meetings of the various NCORP Research Bases to discuss cancer care delivery research topics may be included in the budget.

NOTE: Attendance of investigators at meetings on behalf of the NCORP Research Base, or at special (i.e., non-routine) meetings of committees of the various NCORP Research Bases, should generally be funded through the respective NCORP Research Base, rather than through this award.

2.2.5 *Patient care costs:* NCI will not support costs associated with routine patient care.

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- 2.2.6 *Consortium/Contractual costs:* Separate budget pages with detailed justification of all requested items should be submitted for each consortium agreement and applicable indirect costs should be included.

2.3 Consortium/ Contractual Arrangements:

Consortium arrangements and all other contractual arrangements must be formalized in writing in accordance with applicable NIH Grants Policy requirements available at: http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch15.htm. A statement that the applicant organization and the collaborating organization have established or are prepared to establish a formalized agreement that will ensure compliance with all pertinent NCI, NIH, DHHS, and federal regulations and policies must be included in the application. Also include all pertinent biographical sketches and a list of all other support for all relevant consortium participants.

3. Research Plan

In the "Research Plan" section of the NCORP Community Site application, a Specific Aims page should be provided as well as separate PHS 398 Research Strategy Sections for the 5 sub-sections listed below within the corresponding specified page limits (and the Table of Contents for the Research Plan section of the application should be modified accordingly). The 5 sub-sections are listed below

Table of Contents for NCORP Community Site application

Specific Aims (including Impact Statement) - 1 page

Research Strategy Section for the NCORP Community Site Application:

This section must consist of the sub-sections A.- E. described below.

- A. Organization and Structure- 12 pages
- B. Leadership - 12 pages
- C. Clinical Trials Research Program - 12 pages
- D. Cancer Care Delivery Research Program - 12 pages
- E. Operations/Data Management Core - 12 pages

Other sections of the PHS 398 Research Plan (398 application instructions Part I, Section 5.5), such as the sections for Letters of Support (e.g., Letters of Support , PD(s)/PI(s)) and Multiple Program Director/Principal Investigator (PD/PI) Leadership Plan, remain unmodified and must be completed following standard instructions.

Research Strategy Section for the NCORP Community Site Application

This section must consist of the sub-sections A-E described below.

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3.1 Sub-Section A. Organization and Structure (up to 12 pages)

Organizational Structure for NCORP Research Activities.

Describe the current and/or planned organizational structure under which the applicant proposes to conduct clinical trials and cancer care delivery research. Include an organizational chart.

NCORP Community Sites are expected to function as consortia of the Community Site awardee institution and several partners. Depending on the relationship to the proposed Community Site institution, specific partners are referred to as **NCORP Community Site "components" or "sub-components"**.

Definition of Community Site Component: In the context of NCORP Community Site structure, a "component" refers to a hospital, cancer center, physician practice, or other institution where patients/participants are enrolled on a regular and ongoing basis to the menu of NCI-approved clinical trials available to the NCORP Community Site. In addition, one or more of the NCORP Site components are expected to participate in cancer care delivery research. Community Site awardee will be regarded as a "primary component".

Definition of Community Site Sub-Component: In the context of NCORP Community Site structure, a "sub-component" refers to a practice or organization that contributes to the overall accrual of a component site but is located in a separate geographic location(s), is part of the component's business entity, and is managed by the component.

If the NCORP Community Site applicants propose more than one component or sub-component, each must be listed to be considered part of NCORP. Describe the relationship of component(s)/sub-component(s) to each other and to the NCORP awardee Community Site, if applicable. Include a diagram showing the distance between these entities (including administrative office and shared resources) and location of proposed personnel.

NOTE: Information on the applicant's component(s)/subcomponent(s) may be summarized in a table as described in the Resources Section above.

The applicant should identify at least one component that will participate in cancer care delivery research. Provide rationale to justify why specific component(s) are selected for this role. The component(s) should be able to implement on-site cancer care delivery research, provide organizational data (e.g., financial, service utilization, processes of care) in support of cancer care delivery research, and mentor other component(s) in their NCORP

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awardee network in cancer care delivery research. These capabilities can all be provided by a single component or by more than one component. Alternatively, the various capabilities may be distributed over two or more different components. If the applicant has more than one component designated to participate in cancer care delivery research, describe the relationship of component(s) to each other.

Catchment Area. The applicants must delineate their catchment area. A map of the service area, designating counties or zip codes from which approximately 80 percent of the patients will be drawn, should be provided. Provide an estimate of the percentage of oncologists in the service area that will participate in the NCORP Community Site and a description of patient referral patterns within the catchment area. A description of other cancer care resources in the catchment area (i.e., hospitals, clinics, physicians, cancer centers) that are not part of the application should be included. A description of the study population in the applicant's catchment area should be provided with percentages by gender, race and ethnicity, as well as measures of social deprivation, such as socioeconomic status, poverty status and insurance status. Applications should provide information regarding the percentage of patients in the catchment area for the following age categories: 1-15, 15-39, 40-64, 65+; and percentage of patients in their cancer registries over the age of 65.

Clinical Practice Structure and Partnerships. Describe the types and sizes of the participating components/subcomponent(s) that will be included in the NCORP Community Site (e.g., outpatient/inpatient practices, hospitals/clinics/cancer centers), as well as the number of participating oncologists, primary care and other providers. Describe relationships with primary care and other providers that will be research collaborators with the applicant. Relationships with key community partners (e.g., faith-based organizations, advocacy groups, and community coalitions) and planned strategies to engage the community partners in increasing clinical trials education and outreach and facilitating wider community participation by patients and providers in clinical trials and cancer care delivery research should be described.

Institutional Commitment: All the consortium components' must be fully committed to participation in clinical trials, and, as applicable, cancer care delivery research. These commitments must be supported by appropriate documentation in respective sections of the application.

Note: Include letters of institutional commitment and letters of Intent to Establish a Consortium, if applicable, under Section 4. of Research Plan "Letters of Support". Letters for components participating in cancer care delivery research should indicate the degree to which sites are willing to provide service utilization, claims

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or service encounters, cancer registry, national quality reporting, and financial data. Applicants, whose applications are considered for funding, will be expected to provide fully executed consortium agreements, if applicable, as a Just-in-Time requirement.

Facilities. Briefly describe the salient features of the facilities and other resources available (committed) for use by the proposed Community Site. Appropriate space must be available for administrative activities and personnel to serve as primary locus for data management, quality control, and communication.

3.2 *Sub-Section B. Leadership (up to 12 pages)*

Outline the leadership structure and the roles of PD/PI and other senior investigators. [Note that for applications designating multiple PD(s)/PI(s), a separate section Leadership Plan must also be completed as per standard PHS 398 instructions). If the multiple PDs/PIs option is not chosen, applicants must identify a substitute PD/PI candidate to assure continuity and a smooth transition of leadership i when necessary.

In addition, either the PD/PI (or one of the multiple PDs/PIs) or another senior researcher must be designated to have leadership responsibility for the cancer care delivery research program. The qualifications and experience of these individuals must be described, documenting their respective abilities to organize and manage a community oncology program that includes cancer prevention, control, screening/post-treatment surveillance, treatment and imaging clinical trials and cancer care delivery research as well as experience in accruing patients/participants to clinical trials and/or conducting cancer care delivery research. The application should also describe the strategy used by the PD(s)/PI(s) and the Institutional official to delegate leadership responsibility with respect to the clinical trials and cancer care delivery research selected for activation by the NCORP Community Site and how the responsibility is delegated among Key/Senior individuals.

A mentoring plan or program for leadership development within the NCORP Community Site is recommended. If such a plan exists or is under development, it should be described in the application.

It is expected that the PD(s)/PI(s) of the NCORP Community Site will already be established as leader(s) in some capacity in the community served by the Site. Characterize briefly these leadership roles played by PD(s)/PI(s) and other senior investigators (if applicable). Describe, for example, their relationships with community leaders in government and other organizations with goals related to cancer care including the quality of and disparities in cancer care (e.g., advocacy groups, county/state agencies). The impact of these activities on the success of the NCORP Community Site as well as on the overall community should be described

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including the potential to translate research findings into community oncology practices. In addition, the application should describe the leadership positions held by the PD(s)/PI(s) with affiliated Research Bases and contributions made in that position along with their impact. Parallel descriptions should be given for other Key/Senior personnel, if applicable. Finally, leadership roles of the PD(s)/PI(s) and other Key/Senior Personnel in national research organizations and professional societies should be described.

Other Professional Personnel. The application should propose a committed multi-disciplinary oncology research team of professionals appropriate for its expected clinical trial participation. With regard to cancer care delivery research, the component(s) proposed for participation should have a committed team involving oncologists, primary care and other providers, other professionals (e.g., administrators, care coordinators, genetic counselors), staff responsible for managing databases (e.g., cancer registries, electronic medical records, claims databases) and a senior administrator to facilitate implementation of studies that address organization and processes of care. A description of both teams, how they plan to operate and interact, and how they plan to lend their expertise to achieve the goals of the application should be provided.

3.3 Sub-Section C. Clinical Trial Research Program (up to 12 pages)

Experience. Describe the applicant's experience relative to implementing cancer clinical trials in the applicant's practice setting(s) and provide a detailed summary of the applicant's accrual to NCI-approved cancer prevention, control, screening/post-treatment surveillance, treatment, and imaging clinical trials as well as to any cancer clinical trials sponsored by other non-profit organizations during the past 5 years. In addition, describe the applicant's contributions (if any) during the past 5 years to the research agenda of the Cooperative Groups and CCOP Research Bases with which the applicant has been affiliated.

NOTE: Supplementary information on the applicant's accrual record may be summarized in a table as described in the Resources Section above.

Research Priorities. Describe the plans and approaches for implementing and conducting NCI-approved cancer clinical trials in the practice setting(s) of the community served by the applicant team, including approaches for engaging patients from minority and underserved populations, and hospitals, clinics and other cancer care settings that serve these populations.

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Describe in narrative form the types of cancer prevention, control, screening/post-treatment surveillance, treatment, and imaging clinical trials the applicant expects to activate during the award period and include a description of the processes by which the applicant will select an adequate number of clinical trials to meet or exceed accrual requirements and/or planned accrual goals. The application should also describe why the proposed clinical trial categories are appropriate for the patients/participants in the NCORP Community Site's catchment area.

Include a list of the NCI cancer prevention, control, screening/post-treatment surveillance, treatment, and imaging clinical trials that are currently active as well a list of the clinical trials that the applicant plans on activating during the next year. Applicants who are not current CCOP/MBCCOP award holders should provide a list of the currently active clinical trials that they would expect to activate as an NCORP Community Site if such clinical trials were still open to accrual once NCORP awards are made as well as proposed implementation plans for activating such clinical trials including specifics on patient/participant recruitment, compliance and follow-up, etc.

Describe the readiness and capacity of the consortium components to participate in clinical trials addressing the mechanisms of cancer symptoms and treatment-related toxicities, molecularly-targeted agents to understand toxicities, post-treatment surveillance, underdiagnosis and overdiagnosis, and management of precancerous lesions. The application should also describe readiness and capacity to collect biospecimens and an approach to facilitating understanding and adoption by community-based physicians of genomic medicine and targeted cancer therapies as well as educating cancer patients and at-risk individuals about these modalities.

The applicant's recruitment and retention plans should be described, including outreach efforts and methods for engaging the community it serves, which may involve patient advocates. The plans for recruiting women, racial/ethnic minorities, and underrepresented populations (e.g., elderly, adolescents and young adults patients who are under-and uninsured, and patients who reside in rural or low resourced urban areas) must be described. The information on women and minorities must be included under Section 5.5.7 Inclusion of Women and Minorities.

NOTE: Information on the applicant's currently active NCI clinical trials and/or NCI clinical trials expected to be activated may be summarized in tables as described in the Resources Section above.

Research Base Affiliations. The Research Base affiliations of the NCORP Community Site should be described in the application.

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Applicants without current CCOP or MB-CCOP awards should indicate their plan(s) for affiliations based upon their review of existing Research Base portfolios. Copies of affiliation agreements or Research Base letters of intent to support for applicants, should be included under Section 14. Letters of Support. The rationale for choosing these Research Base affiliations should be discussed. In addition, the application should outline plans for contributing to the scientific agenda of its affiliated Research Bases over the next project period. Examples of contributions might include: participation/membership in Research Base scientific committees or community liaison committees; serving as Chair(s) on cancer clinical trials; authorship of joint publications, etc. The process for eliciting and incorporating community input that informs the Research Base scientific agenda should also be described.

NOTE: Information on the applicant's current and/or planned Research Base affiliations may be summarized in a table as described in the Resources Section above.

Accrual. Each application must include plans for achieving accrual goals to cancer prevention, control, screening/post-treatment surveillance, treatment and imaging clinical trials over the next project period (5 years). Applications must include evidence that the NCORP Community Site can meet or exceed the required annual 80 new patient/participant accruals evenly distributed over the available cancer prevention, control and screening/post-treatment surveillance clinical trials versus treatment and imaging clinical trials, respectively.

3.4 Sub-Section D. Cancer Care Delivery Research Program (up to 12 pages)

Background and Experience. Describe the capabilities to support the implementation of the cancer care delivery research in the following areas: genetic counseling, multidisciplinary care, care coordination/navigation processes, supportive/palliative care and outreach programs for minority/underserved populations. Describe the strategies (if any) used by practitioners and senior management at the institution(s) to support the implementation of cancer care delivery research. Outline the applicant's potential contribution of the requested data to multi-site studies. Mention other strategies considered including allowing staff to participate as subjects of research. Describe the level of proficiency of medical staff in the reporting of high quality medical data. List the participation in institutional, national and/or regional initiatives focused on improving the quality of care such as: American Society of Clinical Oncology Quality Oncology Practice Initiative (QOPI®), Commission of Cancer Rapid Quality Reporting System (RQRS), and Medicare's Physician Quality Reporting System (PQRS)

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NOTE: Information on the capabilities of the component(s) designated for participation in cancer care delivery research in genetic counseling, multidisciplinary care, care coordination/navigation processes, supportive/palliative care and outreach programs for minority/underserved populations may be summarized in a table as described in the Resources Section above.

If applicable, describe the history and experience of the designated component(s) in conducting cancer care delivery research during the past 5 years (e.g., comparative effectiveness research, survey studies). The description should include experience of relevant clinical professionals and other staff working together as a team in implementing cancer care delivery research as well as experience working with and merging multiple datasets (e.g., registry, medical record, financial data) and providing data to outside researchers and entities. Data provided in such studies could include existing secondary data or prospective data collected from patients, practitioners and/or other organizational personnel through surveys, focus group or other methods.

NOTE: Information on the past experience of the component(s) designated for participation in cancer care delivery research may be summarized in a table as described in the Resources Section above.

Research Priorities. The application should identify specific study categories in which the component(s) proposed for participation in cancer care delivery research will participate as well as the processes used by the component(s) for selecting, implementing, and conducting NCI-approved studies. These cancer care delivery research may be observational or interventional in design. Observational studies may address patterns of care or service utilization, alternative organizational structures (e.g., integrated healthcare systems versus free-standing hospitals), programs to improve health behaviors, etc. Interventional studies may address implementation of new technologies (e.g., decision-making tools to support genomically-informed therapies), new approaches for multi-modality therapy planning and delivery, patient navigation and other care processes, incorporation of new types of information (e.g., patient reported information) into clinical decision-making, etc. These studies may also incorporate disparities research questions.

If the designated component(s) have experience in cancer care delivery research, describe the types of studies for which they offer particular capabilities and strengths to the NCORP network. If the designated component(s) are new to cancer care delivery research, describe approaches the institution(s) will use for enhancing their understanding of and preparedness for conducting cancer care

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delivery research. All applicants should also describe the strategies that their designated component(s) will take in the shaping of NCORP's emerging cancer care delivery research agenda.

The application should include a description of the approaches to be used by the designated component(s) for involving oncologists, primary care physicians, other professionals (e.g., administrators, care coordinators, genetic counselors), and staff responsible for managing databases (e.g., cancer registries, electronic medical records, claims databases) in cancer care delivery research. Applicants should also describe plans for the designated component(s) to engage patients from minority/underserved populations, and hospitals, clinics and other cancer care settings that serve these populations.

Provide plans explaining how the designated component(s) will collect and manage data on program characteristics, patterns of care and organizational policies and make these data available to the affiliated Research Bases. These data would be expected to include but not be limited to: descriptions of organizational structures, in-depth information on specialists and specialized programs (e.g., palliative care), service utilization data, billing/financial data, quality monitoring data, and organizational policies such as personnel practices, clinical protocols and reimbursement arrangements. Describe any perceived barriers in the types of data that the designated component(s) would be able to report to investigators for approved studies.

3.5 Sub-Section E. Operations/Data Management Core (up to 12 pages)

Institutional Review Board (IRB). Describe the processes the consortium has in place for ensuring compliance with regulations for IRB approval and informed consent (compliance with 45 CFR 46) related to research involving human subjects. The description may be included under Section 5.5.6 Protection of Human Subjects of the application and cross-referenced to this section of the Research Plan. Describe current (or planned) use of the NCI's [Central IRB](#) for cancer treatment clinical trials from NCTN Network Groups and their local IRBs for cancer prevention, control, and screening clinical trials and cancer care delivery research. Describe the approach for ensuring that IRB(s) with adequate expertise in cancer care delivery research is available.

Operations. Outline the standard operating procedures of the applicant's team for activating clinical trials as well as for recruiting, enrolling and monitoring patients/participants. Describe the infrastructure the applicant has in place to oversee day-to-day operations for conducting clinical trials. Also describe the procedures

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to be implemented at the component(s) proposed for participation in cancer care delivery research for activating studies and recruiting, enrolling and monitoring participants. In addition, describe the plans for communication among physicians and components and incentives for their participation in studies.

Data Management & Quality Assurance. Procedures for data management and investigational drug monitoring must be described in the application. For both clinical trials and cancer care delivery research, address the following items:

- Who is responsible for data management;
- What is the source of records (e.g., hospital, office, clinic, registry);
- How the information will flow (provide flow chart);
- Who will enter data on primary patient records and study forms (e.g., nurses, physicians, data managers, administrators);
- Who will collect and send patient materials (e.g., pathology slides, port films, etc.) to the Research Bases;
- What records (study flow sheets, reminder slips) will be included on patient charts; and
- How data will be transmitted (e.g., batch mode or in real time) and whether mechanisms are in place for electronic data transfer.

In addition, for cancer care delivery research, address the following:

- How data will be obtained from existing repositories such as cancer registries and claims databases; and
- How standard data on organizational characteristics, patterns of care and organizational policies will be assembled.

Describe how data management responsibilities are distributed within and between components/sub-component(s) and the central applicant office, if applicable. Describe how NCI and FDA requirements for investigational drug management are handled. The internal quality assurance plan of the applicant must be described in detail for both clinical trials and cancer care delivery research. Assurance of quality is the joint responsibility of the NCORP Community Site and its affiliated Research Bases. The applicant should describe its policies and procedures for complying with federal regulations related to confidentiality of patient data, including the Health Insurance Portability and Accountability Act (HIPAA) regulations.

Audit Performance. For applicants whose components currently participate or have previously participated in CCOP Research Base clinical trials, a brief description of the overall summary audit(s) results should be provided.

NOTE: The summary audit report information may be summarized in a table as described in the Resources Section

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above.

3.6 Protection of Human Subjects

Applicants should consult the PHS 398/SF424 regarding general instructions on what types of information should be included in the application regarding human subjects research, including the protection of human subjects. **Information on the targeted/planned enrollment table for minorities and members of both genders (as well as children, if applicable), should be based on accrual summarized across all diseases for the planned project period in the competing new application (Type 1), not on a study or disease-specific basis.**

The NCORP Community Site application must address the inclusion of women and minorities and inclusion of children in the clinical research it participates in as required per NIH/NCI Policy. Information on the policies for inclusion of women and minorities is available at:

http://grants.nih.gov/grants/funding/women_min/women_min.htm

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Information on the policies for inclusion of children is available at:

<http://grants.nih.gov/grants/funding/children/children.htm>

<http://www.nih.gov/grants/guide/notice-files/not98-024.html>

3.7 Resource Sharing Plans

Applicants are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS) as provided in the PHS 398 Application Guide with the following modifications:

Generally, Resource Sharing Plans (Data Sharing Plan, [Sharing Model Organisms](#) if applicable, and [Genome Wide Association Studies \(GWAS\)](#) are expected but they are not applicable for this FOA.

4. Appendix Material & Post Submission Materials

Information on the Appendix material that should be provided in the NCORP Community Site application, along with information on the timing of submission of this material and the format in which it should be provided is described in Part 2 – Section I.D. of these Guidelines. Information on post submission materials that may be provided for the NCORP Community Site application is described in Part 2 – Section I.F of these Guidelines.

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5. Just-in-Time Information

The following material must be submitted prior to the award of the Cooperative Agreement for the NCORP Community Site.

5.1 Other Support for Key Personnel

NCI program staff will contact all applicants to be funded to request "Other Support" for Key Personnel, including consortium/contract personnel. "Other Support" includes all financial resources, whether federal, non-federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, Cooperative Agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included. Percent effort should be specified as well as any support that is pending. Information on other support assists the awarding NCI staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating such overlap are to ensure that: (1) sufficient and appropriate levels of effort are committed to the project, (2) there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort, and (3) only funds necessary to the conduct of the approved project are included in the award.

5.2 Training on Human Subjects Protection for Key Personnel

As part of Just-In-Time information, the NCORP Community Site should also submit a roster of Key Personnel and indicate the type of training program on human subjects protection completed by each person listed. The NIH policy on Human Subjects Protection is available at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

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D. NCORP Minority/Underserved Community Site Application

Specific instructions are provided on the following pages for the NCORP Minority/Underserved Community Site application. In general, except where noted below, all applications should conform to the instructions in the PHS 398/SF424.

1. Detailed Budget for Clinical Trial Program for the Initial Budget Period

A separate budget and PHS398/SF424 for clinical trials should be provided.

1.1 Estimation of Total Cost Clinical Trials Budget Request

The total cost budget requested by the NCORP Minority/Underserved Community Site in its application should be based on the two elements described below, using guidelines provided in Part 4 – Appendices – Section IV of these Guidelines:

- (1) Infrastructure funding for the Minority/Underserved Community Site to establish and maintain a clinical research capacity
- (2) Variable “per case management” funding based on an algorithm that estimates the variable costs for data collection and management and biospecimen collection based on the trailing three year average annual credits received by the NCORP Minority/Underserved Community Site for subjects enrolled by all its component sites in cancer treatment, advanced imaging, prevention, control and screening/post-treatment surveillance clinical trials as well as health-related quality of life (HRQOL) studies embedded within treatment and imaging trials and a fixed cost multiplier determined by the historical level of accrual for the NCORP Minority/Underserved Community Site

Minority/Underserved Community Sites that received more than 200 credits annually during the past three years may be eligible to use the “high performance” per case management funding dollar amount (i.e., \$4000). Past experience indicates high accruing sites may need additional resources to compensate for the larger number of patients who must be followed over multiple future years while Community Sites that consistently received less than 200 credits during the past three years may only qualify for the “basic” per case management funding amount (i.e., \$2500). All applicants must provide justification for the amount requested based on actual costs to be incurred by the organization.

1.2 Cost Categories

Once the NCORP Minority/Underserved Community Site applicant has determined the amount of its total cost budget request for

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clinical trials using the guidelines specified in Part 4 – Appendices – Section IV of these Guidelines, the applicant should provide a “level of effort” budget based on the budget categories described below. These categories refer to those contained in the section of the PHS 398/SF424 pertaining to the detailed budget for the initial budget period.

- 1.2.1 **Personnel:** A clinical trials staffing plan for the NCORP Minority/Underserved Community Site, including position descriptions and qualifications should be provided. **NOTE:** Specific job descriptions and qualifications for funded personnel (administrative as well as scientific) should be covered in this budget section and not repeated in the research plan narrative. Precise justification for the amount of effort requested for each is essential, including the following:

- **Investigator Efforts:** Research costs include the time and effort involved in overseeing NCORP clinical trial research activities of the Minority/Underserved Community Site and its participating components.

NOTE: Funding for positions within the senior leadership of a NCORP Research Base (i.e., Executive Medical Officer, Executive Committee positions, Scientific and Administrative Committee Chair/Co-Chair positions, Study Chair positions) should be funded by the Research Base award.

- **Data management:** Research costs include the time and effort involved in accurate collection and submission of clinical trial and HRQOL study data.
- **Scientific Services:** Research costs include the time and effort related to providing specific services such as pathology and radiology review for clinical trials and HRQOL studies.
- **Administration:** Research costs include the time and effort involved in coordinating clinical trial research activities at the NCORP Minority/Underserved Community Site including regulatory activities, implementation of quality assurance and study monitoring procedures and participation in NCORP onsite audit program.

- 1.2.2 **Consultant Costs:** Consultant costs are not usually appropriate in this award, so requests should be justified in detail. These costs include travel, per-diem, and consultant fees, if applicable and within institutional policy.

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- 1.2.3 *Supplies, Equipment, and Other Costs:* Research costs for appropriate supplies, with quantitative justifications based on actual use, should be provided. Significant equipment costs are unusual in this award, and such costs must be justified in detail. The amount of funds requested for equipment should be based on the percent of usage. Research costs due to other expenses include those associated with communication with the various NCORP Research Base and/or Network Groups' offices, the costs of compiling and mailing data and the costs of mailing or handling patient-related specimens, forms, and materials (e.g., slides, X-ray films).
- 1.2.4 *Travel:* Travel for a reasonable number of the NCORP Minority/Underserved component sites' participating investigators, data managers, and nurses to attend the regular meetings of the various NCORP Research Bases and/or Network Groups should be included in the budget.
NOTE: Attendance of investigators at meetings on behalf of the NCORP Research Base and/or Network Groups, or at special (i.e., non-routine) meetings of committees of the various NCORP Research Bases and/or Network Groups, should generally be funded through the respective NCORP Research Base and/or Network Group, rather than through this award.
- 1.2.5 *Patient care costs:* NCI will not support costs associated with routine patient care.
- 1.2.6 *Consortium/Contractual costs:* Separate budget pages with detailed justification of all requested items should be submitted for each consortium agreement and applicable indirect costs should be included.

1.3 Rationale for Budget Policy

NCORP Minority/Underserved Community Sites considered "high performance" sites receive a higher rate for per case data management funding because of the burden of the large number of patients accrued.

1.4 Consortium/ Contractual Arrangements

Consortium arrangements and all other contractual arrangements, including mechanisms for reimbursement of component sites for administration management/data management for patient accrual, must be formalized in writing in accordance with applicable NIH Grants Policy requirements available at:
http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch15.htm.
A statement that the applicant organization and the collaborating organization have established or are prepared to establish a formalized agreement that will ensure compliance with all pertinent

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NCI, NIH, DHHS, and federal regulations and policies must be included in the application.

3. Detailed Budget for Cancer Care Delivery Research for the Initial Budget Period

A single budget and PHS398/SF424 for cancer care delivery research and clinical trials should be provided.

NOTE: The applicant must identify at least one component site that will participate in cancer care delivery research studies. The component site(s) must be able to implement on-site cancer care delivery research studies, provide organizational data (e.g., financial, service utilization, processes of care) in support of cancer care delivery research studies, and mentor other components in their NCORP awardee network in cancer care delivery research. These capabilities can all be provided by a single component site or by more than one component site. Alternatively, the various capabilities may be distributed over two or more different component sites.

2.1 Estimation of Total Cost Cancer Care Delivery Research Budget Request

The total cost budget requested by the NCORP Minority/Underserved Community Site for cancer care delivery research in its application should include the following elements for each component site designated for participation in cancer care delivery research:

1. Costs for overall scientific and management leadership and coordination for research program
2. Costs for study coordinator and data system staff to conduct studies

Because cancer care delivery research was not a focus of activity under the previous Minority-Based CCOP awards, the expectation is that the majority of the Minority/Underserved Community Site budget in the initial award year will be for evaluating and enhancing their informatics and data collection/reporting capabilities with regard to cancer care delivery research at the designated component sites and in training their research and data systems staff in this area of research. In subsequent award years, the funding is expected to move primarily toward supporting participation in specific studies.

At a minimum, Minority/Underserved Community Site funding for cancer care delivery research activities is expected to support approximately 5% time for a lead investigator who provides scientific oversight of the cancer care delivery

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research program and approximately one staff FTE to support data management and study coordination for at least one component site designated for participation in cancer care delivery research. Minority/Underserved Community Sites with (1) one or more component sites with demonstrated experience and capacity in cancer care delivery research; (2) one or more component sites with additional data collection capabilities (e.g., linking registry, medical records and administrative data); and/or (3) more than one component site with the interest and capacity to conduct cancer care delivery research will be candidates for increased levels of funding. The total cost budget request from Community Sites with additional component sites and/or enhanced capacity may qualify for higher levels of funding. The budget justification should clearly delineate the proposed use of funds requested.

2.2 Cost Categories

The applicant should provide a "level of effort" budget based on the guidance above and the budget categories described below. These categories refer to those contained in the section of the PHS 398/SF424 pertaining to the detailed budget for the initial budget period.

2.2.1 *Personnel:* A cancer care delivery research staffing plan for the component site(s) designated to participate in cancer care delivery research, including position descriptions and qualifications should be provided. **NOTE:** Specific job descriptions and qualifications for funded personnel should be covered in this budget section and not repeated in the research plan narrative. Precise justification for the amount of effort requested for each is essential, including the following:

- **Investigator Efforts:** Research costs include the time and effort involved in overseeing NCORP cancer care delivery research activities of the participating component site(s).

NOTE: Funding for positions within the senior leadership of a NCORP Research Base for cancer care delivery research (i.e., Scientific and Administrative Committee Chair/Co-Chair positions, Study Chair positions) should be funded by the Research Base award.

- **Data management:** Research costs include the time and effort involved in accurate collection and submission of cancer care delivery research study data.
- **Scientific Services:** Research costs include the time and effort related to providing specific services such as

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informatics support or mentoring investigators of other component sites within their NCORP Minority/Underserved Community Site network in the conduct of cancer care delivery research.

- **Administration:** Research costs include the time and effort involved in coordinating cancer care delivery research activities at the participating component site(s), including regulatory activities, implementation of quality assurance and study monitoring procedures and participation in NCORP onsite audit programs.
- **NCORP-wide Repository Data:** Research costs include the time and effort involved in the collection and reporting of NCORP-wide repository data to affiliated Research Bases.

2.2.2 *Consultant Costs:* Consultant costs are not usually appropriate in this award, so requests should be justified in detail. These costs include travel, per-diem, and consultant fees, if applicable and within institutional policy.

2.2.3 *Supplies, Equipment, and Other Costs:* Research costs for appropriate supplies, with quantitative justifications based on actual use, should be provided. Significant equipment costs are unusual in this award, and such costs must be justified in detail. The amount of funds requested for equipment should be based on the percent of usage. Research costs due to other expenses include those associated with communication with the various NCORP Research Bases' offices, the costs of compiling and mailing data and the costs of mailing or handling patient-related specimens, forms, and materials (e.g., registry records, medical record abstraction forms).

2.2.4 *Travel:* Travel for the cancer care delivery research lead investigator and study coordination or data management staff from the participating component site(s) to attend meetings of the various NCORP Research Bases to discuss cancer care delivery research topics may be included in the budget.

NOTE: Attendance of investigators at meetings on behalf of the NCORP Research Base, or at special (i.e., non-routine) meetings of committees of the various NCORP Research Bases, should generally be funded through the respective NCORP Research Base, rather than through this award.

2.2.5 *Patient care costs:* NCI will not support costs associated with routine patient care.

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2.2.6 *Consortium/Contractual costs:* Separate budget pages with detailed justification of all requested items should be submitted for each consortium agreement and applicable indirect costs should be included.

2.3 Consortium/ Contractual Arrangements:

Consortium arrangements and all other contractual arrangements must be formalized in writing in accordance with applicable NIH Grants Policy requirements available at: http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch15.htm. A statement that the applicant organization and the collaborating organization have established or are prepared to establish a formalized agreement that will ensure compliance with all pertinent NCI, NIH, DHHS, and federal regulations and policies must be included in the application. Also include all pertinent biographical sketches and a list of all other support for all relevant consortium participants.

3. Research Plan

In the "Research Plan" section of the NCORP Minority/Underserved Community Site application, a Specific Aims page should be provided as well as separate PHS 398 Research Strategy Sections for the 5 sub-sections listed below within the corresponding specified page limits (and the Table of Contents for the Research Plan section of the application should be modified accordingly). The 5 sub-sections are listed below

Table of Contents for NCORP Minority/Underserved Community Site application

Specific Aims (including Impact Statement) - 1 page

Research Strategy Section for the NCORP Minority/Underserved Community Site Application:

This section must consist of the sub-sections A.- E. described below.

- A. Organization and Structure- 12 pages
- B. Leadership - 12 pages
- C. Clinical Trials Research Program - 12 pages
- D. Cancer Care Delivery Research Program - 12 pages
- E. Operations/Data Management Core - 12 pages

Other sections of the PHS 398 Research Plan (398 application instructions Part I, Section 5.5), such as the sections for Letters of Support (e.g., Letters of Support , PD(s)/PI(s)) and Multiple Program Director/Principal Investigator (PD/PI) Leadership Plan, remain unmodified and must be completed following standard instructions.

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All instructions in the PHS 398 Application Guide must be followed, with the following additional instructions:

Research Strategy Section for the NCORP Minority/Underserved Community Site Application

This section must consist of the sub-sections A-E described below.

3.1 Sub-Section A. Organization and Structure (up to 12 pages)

Organizational Structure for NCORP Research Activities.

Describe the current and/or planned organizational structure under which the applicant proposes to conduct clinical trials and cancer care delivery research. Include an organizational chart.

NCORP Minority/Underserved Community Sites are expected to function as consortia of the Minority/Underserved Community Site awardee institution and several partners. Depending on the relationship to the proposed Minority/Underserved Community Site institution, specific partners are referred to as **NCORP Community Site "components" or "sub-components"**.

Definition of Community Site Component: In the context of NCORP Minority/Underserved Community Site structure, a "component" refers to a hospital, cancer center, physician practice, or other institution where patients/participants are enrolled on a regular and ongoing basis to the menu of NCI-approved clinical trials available to the NCORP Minority/Underserved Community Site. In addition, one or more of the NCORP Site components are expected to participate in cancer care delivery research. Minority/Underserved Community Site awardee will be regarded as a "primary component".

Definition of Community Site Sub-Component: In the context of NCORP Community Site structure, a "sub-component" refers to a practice or organization that contributes to the overall accrual of a component site but is located in a separate geographic location(s), is part of the component's business entity, and is managed by the component.

If the NCORP Community Site applicants propose more than one component or sub-component, each must be listed to be considered part of NCORP. Describe the relationship of component(s)/sub-component(s) to each other and to the NCORP awardee Community Site, if applicable. Include a diagram showing the distance between these entities (including administrative office and shared resources) and location of proposed personnel.

NOTE: Information on the applicant's component(s)/sub-

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component(s) may be summarized in a table as described in the Resources Section above.

The applicant should identify at least one component that will participate in cancer care delivery research and provide support for why the component(s) was (were) selected. The component(s) should be able to implement on-site cancer care delivery research, provide organizational data (e.g., financial, service utilization, processes of care) in support of cancer care delivery research, and mentor other components in their NCORP awardee network in cancer care delivery research. These capabilities can all be provided by a single component or by more than one component. Alternatively, the various capabilities may be distributed over two or more different components. If the applicant has more than one component designated to participate in cancer care delivery research, describe the relationship of component(s) to each other.

Catchment Area. The applicants must delineate their catchment area. A map of the service area, designating counties or zip codes from which approximately 80 percent of the patients will be drawn, should be provided. Provide an estimate of the percentage of oncologists in the service area that will participate in the NCORP Minority/Underserved Community Site and a description of patient referral patterns within the catchment area. A description of other cancer care resources in the catchment area (i.e., hospitals, clinics, physicians, cancer centers) that are not part of the application should be included. A description of the study population in the applicant's catchment area should be provided with percentages by gender, race and ethnicity, as well as measures of social deprivation, such as socioeconomic status, poverty status and insurance status. Applications should provide information regarding the percentage of patients in the catchment area for the following age categories: 1-15, 15-39, 40-64, 65+; and percentage of patients in their cancer registries over the age of 65.

Clinical Practice Structure and Partnerships. Describe the types and sizes of the participating components/sub-component(s) that will be included in the NCORP Minority/Underserved Community Site (e.g., outpatient/inpatient practices, hospitals/clinics/ cancer centers), as well as the number of participating oncologists, primary care and other providers. Describe relationships with primary care and other providers that will be research collaborators with the applicant. Relationships with key community partners (e.g., faith-based organizations, advocacy groups, and community coalitions) and planned strategies to engage the community partners in increasing clinical trials education and outreach and facilitating wider community participation by patients and providers in clinical trials and cancer care delivery research should be described.

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Access to Minority and Underserved Populations. NCORP priorities include an emphasis on research questions that address the cancer care needs of racial and ethnic minorities, rural populations and other underserved groups (e.g., elderly, adolescents and young adults and populations who are underinsured and uninsured or reside in low-resourced urban areas). The application must describe the existing (and potentially available for enrollment) pools of individuals in these populations that are at high risk of developing cancer. Describe the pattern of care for minority and underserved populations in the applicant's catchment area and describe the applicant's experience serving these populations in cancer and related care.

Institutional Commitment. All the consortium components must be fully committed to participation in clinical trials, and, as applicable, cancer care delivery research. These commitments must be supported by appropriate documentation in respective sections of the application.

NOTE: Include letters of institutional commitment and letters of Intent to Establish a Consortium, if applicable, under Section 4. of Research Plan "Letters of Support." Letters for component sites participating in cancer care delivery research should indicate the degree to which sites are willing to provide service utilization, claims or service encounters, cancer registry, practice (e.g., national quality reporting), and financial data. Applicants, whose applications are considered for funding, will be expected to provide fully executed consortium agreements, if applicable, as a Just-in-Time requirement.

Facilities. Briefly describe the salient features of the facilities and other resources available (committed) for use by the proposed Minority/Underserved Community Site. Appropriate space must be available for administrative activities and personnel to serve as primary locus for data management, quality control, and communication.

3.2 Sub-Section B. Leadership (up to 12 pages)

Outline the leadership structure and the roles of PD/PI and other senior investigators. [Note that for applications designating multiple PD(s)/PI(s), a separate section Leadership Plan must also be completed as per standard PHS 398 instructions). If the multiple PDs/PIs option is not chosen, applicants must identify a substitute PD/PI candidate to assure continuity and a smooth transition of leadership i when necessary.

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In addition, either the PD/PI (or one of the multiple PDs/PIs) or another senior researcher must be designated to have leadership responsibility for the cancer care delivery research program. The qualifications and experience of these individuals must be described, documenting their respective abilities to organize and manage a community oncology program that includes cancer prevention, control, screening/post-treatment surveillance, treatment and imaging clinical trials and cancer care delivery research as well as experience in accruing patients/participants to clinical trials and/or conducting cancer care delivery research. The application should also describe the strategy used by the PD(s)/PI(s) and the Institutional official to delegate leadership responsibility with respect to the clinical trials and cancer care delivery research selected for activation by the NCORP Community Site and how the responsibility is delegated among Key/Senior individuals.

A mentoring plan or program for leadership development within the NCORP Community Site is recommended. If such a plan exists or is under development, it should be described in the application.

It is expected that the PD(s)/PI(s) of the NCORP Community Site will already be established as leader(s) in some capacity in the community served by the Site. Characterize briefly these leadership roles played by PD(s)/PI(s) and other senior investigators (if applicable). Describe, for example, their relationships with community leaders in government and other organizations with goals related to cancer care including the quality of and disparities in cancer care (e.g., advocacy groups, county/state agencies). The impact of these activities on the success of the NCORP Community Site as well as on the overall community should be described including the potential to translate research findings into community oncology practices. In addition, the application should describe the leadership positions held by the PD(s)/PI(s) with affiliated Research Bases and contributions made in that position along with their impact. Parallel descriptions should be given for other Key/Senior personnel, if applicable. Finally, leadership roles of the PD(s)/PI(s) and other Key/Senior Personnel in national research organizations and professional societies should be described.

Other Professional Personnel. The application should propose a committed multi-disciplinary oncology research team of professionals appropriate for its expected clinical trial participation. With regard to cancer care delivery research, the component(s) proposed for participation should have a committed team involving oncologists, primary care and other providers, other professionals (e.g., administrators, care coordinators, genetic counselors), staff responsible for managing databases (e.g., cancer registries, electronic medical records, claims databases) and a senior administrator to facilitate implementation of studies that address organization and

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processes of care. A description of both teams, how they plan to operate and interact, and how they plan to lend their expertise to achieve the goals of the application should be provided.

3.3 Sub-Section C. Clinical Trial Research Program (up to 12 pages)

Experience. Describe the applicant's experience relative to implementing cancer clinical trials in the applicant's practice setting(s) and provide a detailed summary of the applicant's accrual to NCI-approved cancer prevention, control, screening, treatment, and imaging clinical trials as well as quality-of-life studies embedded within them, and to any cancer clinical trials sponsored by other non-profit organizations during the past 5 years. In addition, describe the applicant's contributions (if any) during the past 5 years to the research agenda of the Cooperative Groups and CCOP Research Bases with which the applicant has been affiliated.

NOTE: Information on the applicant's accrual record may be summarized in a table as described in the Resources Section above.

Research Priorities. Describe the priorities and approaches for implementing and conducting NCI-approved cancer clinical trials in the practice setting(s) of the community served by the applicant team, including approaches for engaging patients from minority and underserved populations, and hospitals, clinics and other cancer care settings that serve these populations.

Describe in narrative form the types of cancer prevention, control, screening, treatment, and imaging clinical trials the applicant expects to activate during the award period and include a description of the processes by which the applicant will select an adequate number of clinical trials to meet or exceed accrual requirements and/or planned accrual goals. The application should also describe why the proposed clinical trial categories are appropriate for the patients/participants in the NCORP Minority/Underserved Community Site's catchment area.

Include a list of the NCI cancer prevention, control, screening, treatment and imaging clinical trials as well as quality-of-life studies embedded within them that are currently active as well a list of the clinical trials that the applicant plans on activating during the next year. Applicants who are not current CCOP/MBCCOP award holders should provide a list of the currently active clinical trials that they would expect to activate as an NCORP Minority/Underserved Community Site if such clinical trials were still open to accrual once NCORP awards are made as well as proposed implementation plans for activating such clinical trials including specifics on patient/participant recruitment, compliance and follow-up, etc.

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Describe the readiness and capacity of their components to participate in clinical trials addressing the mechanisms of cancer symptoms and treatment-related toxicities, molecularly-targeted modalities, post-treatment surveillance, under-diagnosis and over-diagnosis, and management of precancerous lesions. The application should also describe readiness and capacity to collect biospecimens and an approach to facilitating understanding and adoption by community-based physicians of genomic medicine and targeted cancer therapies as well as educating cancer patients and at-risk individuals about these modalities.

The applicant's recruitment and retention plans should be described, including outreach efforts and methods for engaging the community it serves, which may involve patient advocates. The plans for recruiting women, racial/ethnic minorities, and underrepresented populations (e.g., elderly, adolescents and young adults patients who are under- and uninsured, and patients who reside in rural or low resourced urban areas) must be described. The information on women and minorities must be included under Section 5.5.7 Inclusion of Women and Minorities.

NOTE: Information on the applicant's currently active NCI clinical trials and/or NCI clinical trials expected to be activated may be summarized in tables as described in the Resources Section above.

Research Base Affiliations. The Research Base affiliation(s) of the NCORP Minority/Underserved Community Site should be described in the application. Applicants without current CCOP or MB-CCOP awards should indicate their plan(s) for affiliations based upon their review of existing Research Base portfolios. Copies of affiliation agreements or Research Base letters of intent to support for applicants, should be included under Section 14. Letters of Support. The rationale for choosing these Research Base affiliations should be discussed. In addition, the application should outline plans for contributing to the scientific agenda of its affiliated Research Bases over the next project period, in particular with regard to the integration of disparities-focused research questions. Additional examples of contributions might include such activities as: participation/membership in Research Base scientific committees, community liaison committees, disparities/underserved committees; serving as Chair(s) on cancer clinical trials; authorship of joint publications, etc. The process for eliciting and incorporating community input that informs the Research Base scientific agenda should also be described.

NOTE: Information on the applicant's current and/or planned Research Base affiliations may be summarized in a table as described in the Resources Section above.

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Accrual Plans. Each application must include plans for achieving accrual goals to cancer prevention, control, screening/post-treatment surveillance, treatment, and imaging clinical trials over the next project period (5 years). Applications must include evidence that the NCORP Minority/Underserved Community Site can meet or exceed the required annual 80 new patient/participant accruals evenly distributed over the available cancer prevention, control, and screening clinical trials versus treatment and imaging clinical trials, respectively. Under special circumstances, a NCORP Minority/Underserved Community Site (excluding eligible NCI-Designated Cancer Centers) may be allowed to reach the required annual 80 new participant/patient accruals by the end of the project period.

3.4 Sub-Section D. Cancer Care Delivery Research Program (up to 12 pages)

Background and Experience. Describe the capabilities to support the implementation of the cancer care delivery research in the following areas: genetic counseling, multidisciplinary care, care coordination/navigation processes, supportive/palliative care and outreach programs for minority/underserved populations. Describe the strategies (if any) used by practitioners and senior management at the institution(s) to support the implementation of cancer care delivery research. Outline the applicant's potential contribution of the requested data to multi-site studies. Mention other strategies considered including allowing staff to participate as subjects of research. Describe the level of proficiency of medical staff in the reporting of high quality medical data. List the participation in institutional, national and/or regional initiatives focused on improving the quality of care such as: American Society of Clinical Oncology Quality Oncology Practice Initiative (QOPI®), Commission of Cancer Rapid Quality Reporting System (RQRS), and Medicare's Physician Quality Reporting System (PQRS)

NOTE: Information on the capabilities of the component(s) designated for participation in cancer care delivery research in genetic counseling, multidisciplinary care, care coordination/navigation processes, supportive/palliative care and outreach programs for minority/underserved populations may be summarized in a table as described in the Resources Section above.

If applicable, describe the history and experience of the designated component(s) in conducting cancer care delivery research during the past 5 years (e.g., comparative effectiveness research, survey studies). The description should include experience of relevant clinical professionals and other staff working together as a team in implementing cancer care delivery research as well as experience working with and merging multiple datasets (e.g., cancer registry,

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medical record, financial data) and providing data to outside researchers and entities. Data provided in such studies could include existing secondary data or prospective data collected from patients, practitioners and/or other organizational personnel through surveys, focus group or other methods.

NOTE: Information on the past experience of the component(s) designated for participation in cancer care delivery research may be summarized in a table as described in the Resources Section above.

Research Priorities. The application should identify specific study categories in which the component(s) proposed for participation in cancer care delivery research will participate as well as the processes used by the component(s) for selecting, implementing, and conducting NCI-approved studies. These cancer care delivery research may be observational or interventional in design. Observational studies may address patterns of care or service utilization, alternative organizational structures (e.g., integrated healthcare systems versus free-standing hospitals), programs to improve health behaviors, etc. Interventional studies may address implementation of new technologies (e.g., decision-making tools to support genomically-informed therapies), new approaches for multi-modality therapy planning and delivery, patient navigation and other care processes, incorporation of new types of information (e.g., patient reported information) into clinical decision-making, etc. These studies may also incorporate disparities research questions and be specific to hospitals, clinics and other cancer care settings that serve predominantly minority and/or underserved populations.

If the designated component(s) have experience in cancer care delivery research, describe the types of studies for which they offer particular capabilities and strengths to the NCORP network. If the designated component(s) are new to cancer care delivery research, describe approaches the institution(s) will use for enhancing their understanding of and preparedness for conducting cancer care delivery research. All applicants should also describe the strategies that their designated component(s) will take in the shaping of NCORP's emerging cancer care delivery research agenda and integrating disparities-focused research questions. Minority/Underrepresented Community Site applicants must state how their organizational setting provides a unique opportunity to enhance the understanding of cancer care delivery in underserved populations.

The application should include a description of the approaches to be used by the designated NCORP component(s) for engaging oncologists, primary care physicians, other professionals (e.g., administrators, care coordinators, genetic counselors), and staff responsible for managing databases (e.g., cancer registries, electronic medical records, claims databases) in cancer care delivery research. Applicants should also describe plans for the designated component(s)

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to engage patients from minority/underserved populations, and hospitals, clinics, and other cancer care settings that serve these populations.

Provide plans explaining how the designated component(s) will collect and manage data on program characteristics, patterns of care, and organizational policies and make these data available to the Research Bases. These data would be expected to include but not be limited to: descriptions of organizational structures, in-depth information on specialists and specialized programs (e.g., palliative care), service utilization data, billing/financial data, quality monitoring data, and organizational policies such as personnel practices, clinical protocols and reimbursement arrangements. Describe any perceived barriers in the types of data that the designated component(s) would be able to report to investigators for approved studies.

3.5 Sub-Section E. Operations/Data Management Core (up to 12 pages)

Institutional Review Board (IRB). Describe the processes the consortium has in place for ensuring compliance with regulations for IRB approval and informed consent (compliance with 45 CFR 46) related to research involving human subjects. The description may be included under Section 5.5.6 Protection of Human Subjects of the application and cross-referenced to this section of the Research Plan. Describe the approach for ensuring that an IRB with adequate expertise in cancer care delivery research is available.

Operations. Outline the standard operating procedures of the applicant's team for activating clinical trials as well as for recruiting, enrolling and monitoring patients/ participants. Describe the infrastructure the Site has in place to oversee day-to-day operations for conducting clinical trials. Also describe the procedures to be implemented at the component(s) proposed for participation in cancer care delivery research for activating studies and recruiting, enrolling and monitoring participants. In addition, describe the plans for communication among physicians and components and incentives for their participation in studies. Applicants should describe how oversight for all NCI- supported research activities at all component sites is provided.

Data Management & Quality Assurance. Procedures for data management and investigational drug monitoring must be described in the application. For both clinical trials and cancer care delivery research, address the following items:

- Who is responsible for data management;
- What is the source of records (e.g., hospital, office, clinic,

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- registry);
- How the information will flow (provide flow chart);
- Who will enter data on primary patient records and study forms (e.g., nurses, physicians, data managers, administrators);
- Who will collect and send patient materials (e.g., pathology slides, port films, etc.) to the Research Bases;
- What records (study flow sheets, reminder slips) will be included on patient charts; and
- How data will be transmitted (e.g., batch mode or in real time) and whether mechanisms are in place for electronic data transfer?

In addition, for cancer care delivery research, address the following:

- How data will be obtained from existing repositories such as cancer registries and claims databases; and
- How standard data on organizational characteristics, patterns of care and organizational policies will be assembled.

Describe how data management responsibilities are distributed within and between components/sub-component(s) and the central applicant office, if applicable. Describe how NCI and FDA requirements for investigational drug management are handled. The internal quality assurance plan of the applicant must be described in detail for both clinical trials and cancer care delivery research. Assurance of quality is the joint responsibility of the NCORP Minority/Underserved Community Site and its affiliated Research Bases. The applicant should describe its policies and procedures for complying with federal regulations related to confidentiality of patient data, including the Health Insurance Portability and Accountability Act (HIPAA) regulations.

Audit Performance. For applicants whose components that currently participate or have previously participated in CCOP Research Base trials, a brief description of the overall summary audit(s) results should be provided.

NOTE: The summary audit report information may be summarized in a table as described in the Resources Section above.

3.6 Protection of Human Subjects

Applicants should consult the PHS 398/SF424 regarding general instructions on what types of information should be included in the application regarding human subjects research, including the protection of human subjects. **Information on the targeted/planned enrollment table for minorities and members of both genders (as well as children, if applicable), should be based on accrual summarized across all diseases for the planned project period in the competing new application (Type 1), not on a study or disease-specific basis.**

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The NCORP Minority/Underserved Community Site application must address the inclusion of women and minorities and inclusion of children in the clinical research it participates in as required per NIH/NCI Policy. Information on the policies for inclusion of women and minorities is available at:

http://grants.nih.gov/grants/funding/women_min/women_min.htm

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Information on the policies for inclusion of children is available at:

<http://grants.nih.gov/grants/funding/children/children.htm>

<http://www.nih.gov/grants/guide/notice-files/not98-024.html>

3.7 Resource Sharing Plans

Applicants are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS) as provided in the PHS 398 Application Guide with the following modifications:

Generally, Resource Sharing Plans (Data Sharing Plan, [Sharing Model Organisms](#) if applicable, and [Genome Wide Association Studies \(GWAS\)](#) are expected but they are not applicable for this FOA.

4. Appendix Material & Post Submission Materials

Information on the Appendix material that should be provided in the NCORP Minority/Underserved Community Site application, along with information on the timing of submission of this material and the format in which it should be provided is described in Part 2 – Section I.D. of these Guidelines. Information on post submission materials that may be provided for the NCORP Minority/Underserved Community Site application is described in Part 2 – Section I.F of these Guidelines.

5. Just-in-Time Information

The following material must be submitted prior to the award of the Cooperative Agreement for the NCORP Minority/Underserved Community Site.

5.1 Other Support for Key Personnel

NCI program staff will contact all applicants to be funded to request “Other Support” for Key Personnel, including consortium/contract personnel. “Other Support” includes all financial resources, whether federal, non-federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, Cooperative Agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included. Percent effort should be specified as well as any support that is pending. Information on other support assists the awarding

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NCI staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating such overlap are to ensure that: (1) sufficient and appropriate levels of effort are committed to the project, (2) there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort, and (3) only funds necessary to the conduct of the approved project are included in the award.

5.2 Training on Human Subjects Protection for Key Personnel

As part of Just-In-Time information, the NCORP Minority/Underserved Community Site should also submit a roster of Key Personnel and indicate the type of training program on human subjects protection completed by each person listed. The NIH policy on Human Subjects Protection is available at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

III. Description of Review Process and Review Criteria for New and Competing Applications

A. General Information

1. Role of Peer Review and Review Policies

All applications for the key components of NCORP are submitted and reviewed in the same award cycle. The role of peer review is to assess the extent to which each key component of NCORP has and/or is likely to promote excellence in the conduct of prevention, control and screening/post-treatment surveillance trials as well as cancer care delivery research studies. clinical treatment and advanced imaging studies that may lead to a reduction in the incidence of morbidity and mortality attributable to cancer. The focus of the review is on the ability of each key component of the NCORP to help develop, implement, and conduct meritorious clinical trials, especially definitive late phase, multi-institutional trials as well as cancer care delivery studies. All applications will be reviewed based on individual review criteria categories for each of the key components of NCORP which include an assessment of the application's strength to contribute to the NCORP as a whole. In particular, NCORP Research Base applications , will be reviewed not only for their overall research strategy and scientific impact, but also on their contributions to the science of and accrual to clinical trials conducted across the entire NCORP Program and the strength of their collaborations with other NCORP key components.

The NCI Scientific Review Officer (SRO) serves as the Designated Federal Official (DFO) with legal responsibility for managing the review and ensuring that the review is conducted according to relevant laws, regulations, policies, and established NIH and NCI policies and procedures. The SRO provides guidance and direction with respect to review policies, procedures and criteria; the functions of the NCI staff; conflict of interest policies; implications of the Privacy Act; the need for confidentiality of the proceedings; the necessity of addressing gender, minority, and children representation in clinical study populations; and other policy and logistical matters. During the review, the NCORP Lead Program Director serves as a resource, as needed, concerning the history and development of NCORP and other relevant programmatic matters.

- The NCI is committed to the conduct of impartial, high-quality peer review of grant applications submitted by the scientific community and to the maintenance of an objective review process.
- The Division of Extramural Activities, NCI, which is responsible for managing the peer review of NCORP applications, is organizationally independent from the NCI extramural program

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Description of Review Process and Review Criteria for New and Competing Applications: General Information

units. The Division of Extramural Activities has responsibility for and autonomy in the conduct of review activities.

- The conduct of peer review of NCORP applications shall be in all particulars consistent with, and subject to, applicable NIH and PHS peer review practices and policies.
- NCI SROs are responsible for managing the scientific and technical review of NCORP applications, including the selection of reviewers; management of Special Emphasis Panels (SEPs); and the documentation of review panel findings and recommendations.
- The responsibility for communications between the applicant and NCI staff changes during the various phases of the application process. Prior to submission of the application, NCI/DCP staff members are the appropriate contact. From submission of the application until the peer review has been completed, all contacts should be made through the SRO.
- Following the peer review, NCI/DCP staff members again become the contact for communications with the applicant.
- Efforts are made to avoid both real and apparent conflicts of interest in review of NCORP applications. In addition, the confidentiality of both review materials and reviewer deliberations is maintained. Direct contact between applicants and reviewers is prohibited. Instead, any questions or concerns should be brought to the attention of appropriate NCI staff as indicated above.
- To maintain the focus of the peer review process on scientific merit, previous and current pay lines and funding policies are not discussed and are not relevant.

2. Application Receipt and Referral Process

NCORP applications are received and processed initially by the NIH Center for Scientific Review (CSR) and are assigned to NCI. The NCI referral office subsequently assigns the application to the Community Oncology and Prevention Trials Research Group in NCI/DCP. Finally, Division of Extramural Activities review staff group NCORP applications for review based on the three (3) key component categories of NCORP (i.e., Research Bases, Community Sites and Minority/Underserved Community Sites) and recruit appropriate reviewers for Special Emphasis Panel(s) or SEP(s) as needed to review the different categories of key components of NCORP depending on the expertise needed. **In general, the reviewers will need to assess the value of the applications from the perspective of how the application contributes to the clinical research of NCORP as a whole.**

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Description of Review Process and Review Criteria for New and Competing Applications: General Information

3. Application Administrative Review

Upon receipt, the SRO reviews the application for conformance to applicable NIH and PHS policies and Program Staff accepts the application based upon responsiveness to NCORP Guidelines. If there are extensive deficiencies in the structure, organization or format of the application, or the application fails to address required NIH policies in ways that cannot be resolved quickly, the application will be returned to the applicant without further consideration.

4. Review Format

All review panels are constituted as SEPs. The SEP reviewers evaluate and score general and relevant specific review criteria as appropriate for applications for each key component of the NCORP and then assign an overall impact/priority score to the entire application.

The SEP membership will include (a) senior investigators, many of whom have experience with cancer prevention/control trials (especially late phase clinical trials) and cancer care delivery research. These individuals will also be knowledgeable about clinical trial networks and organizations in oncology and who can view the proposed science from an overall perspective, and be specialists for specific scientific areas (e.g., statistics, data management, translational science, radiotherapy, imaging, health services, health economist and cancer disparities). In organizing the review panel membership, conflicts of interest, either real or apparent, will be managed according to NIH policy.

The SEP review will be based on the written applications submitted only.

The SEP will convene in a face-to-face meeting (F2F) of reviewers in the Washington, DC, metropolitan area or elsewhere at the convenience of the reviewers. **Senior NCI/DCP staff will be available to provide clarification upon SRO's request during orientation for reviewers of NCORP.**

The SRO will provide an introductory orientation on NIH and NCI review policies and procedures and administrative and logistic matters relating to the review. Then, each application will be evaluated by the reviewers. The reviewers will evaluate and rate the general and relevant specific review criteria as appropriate for applications for each key component of NCORP. **The reviewers will need to assess the value of each application as to how it contributes to the clinical and cancer care delivery research of NCORP as a whole. The review panel will then assign the final overall impact/priority score to the each application.**

NCI SROs prepare the summary statement using the minimally edited reviewers' comments as well as summaries of the discussion.

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Description of Review Process and Review Criteria for New and Competing Applications:

5. Selection of Reviewers

The size and composition of the SEP will be determined by the particular details of the applications to be reviewed. It is the responsibility of the SRO to make these determinations based upon thorough understanding of the work proposed in the applications and consultation with NCI/DCP and DCCPS staff and other NCI review staff, as appropriate. The review panel members are recruited based on the scientific areas, approaches, and administrative expertise needed to evaluate the applications. It is anticipated that the SEP convened for NCORP reviews in the future will therefore change every review cycle.

Since clinical trials are based on outcome endpoints for human subjects, the SEP will also include one or more patient/consumer advocates in the review group. These individuals, who have full reviewers' rights, often address clinical or population-based study issues related to protection, recruitment and retention of human subjects in the proposed research that is essential for the success of NCORP.

In identifying prospective qualified reviewers, the SRO takes full advantage of many available resources, including existing databases of experienced reviewers, lists of grantees and contractors, and consultation with recognized authorities in the scientific community. The SEP roster will be available on the NIH Web site approximately 30 days before the review meeting, but is subject to change. All review-related communications with actual or potential reviewers are through the SRO.

The Chairperson of the review panel will generally be a senior investigator experienced in the review of complex multidisciplinary, multi-institutional clinical trials, especially late phase clinical trials, and generally knowledgeable about clinical trial networks/organizations as well as the scientific areas to be reviewed.

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Description of Review Process and Review Criteria for New and Competing Applications: Review Criteria

B. Review Criteria

1. General Information on Review Criteria and Evaluation for All Key Components of the NCORP

The five core review criteria for an application for any of the key components of NCORP are Significance, Investigators, Innovation, Approach, and Environment (see NIH Guide Notice **NOT-OD-09-025** at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-024.html>).

The sections below give more detail about how these review criteria are applied for each key component of NCORP. In addition, some of the key components of NCORP may have additional specific review criteria that may or may not be scored separately.

The emphasis of this FOA is on the ability of the proposed Research Base to provide strong, competent, and comprehensive scientific and statistical leadership for developing, implementing, and analyzing multi-institutional cancer prevention, control, and screening/post-treatment surveillance clinical trials, quality-of-life studies embedded within treatment and imaging clinical trials and studies on cancer care delivery. Integration of individual functional components and their ability to interact with other NCORP awardees is particularly important. In their written critiques, reviewers will be asked to comment on each of the criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these areas of emphasis. Each of the review criteria will be addressed and considered in assigning the overall impact/priority score, and weighted as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high impact/priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to move a field forward.

The emphasis of the review criteria for all the three (3) key components of NCORP is on the capabilities and experience of the applicant team to successfully address the specific roles of the key component in the development, organization, coordination, conduct, and/or support for future NCORP trials, including large scale definitive clinical trials and cancer care delivery research studies.. As all applications submitted in response to the initial Funding Opportunity Announcements (FOAs) for NCORP will be "new" applications, those aspects will be largely evaluated based on the prior performance and productivity of the applicants. These capabilities and commensurate performance/productivity must be appropriate and consistent with specific requirements stated in the FOAs with reference to these Guidelines.

The required capabilities and experience are expected to reflect the properly documented successful performance of the applicant team under the former NCI Community Clinical Oncology Program (i.e. CCOP Research Bases or equivalent large-scale NIH or other non-profit clinical

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Description of Review Process and Review Criteria for New and Competing Applications: Review Criteria

trials networks or programs for the specific key component. Reviewers will be using this information as benchmarks in evaluating all aspects of an application. In order to provide information on prior performance and productivity, applicants should provide information related to performance/productivity in the 5 years prior to the application receipt date (i.e., January 2008 through June 2013).

The complete review criteria for each of the three (3) key components of NCORP are presented in the next sections.

2. Specific Review Criteria for Each of the Key Components of the NCORP

2.1 Criteria for NCORP Research Base

Only the review criteria described below (and the Additional Review Criteria – Overall listed in Part 2 – Section III.B.3.) will be considered in the review process for an application for a NCORP Research Base. As part of the [NIH mission](#), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

The emphasis of this FOA is on the ability of the proposed Research Base to provide strong, competent, and comprehensive scientific and statistical leadership for developing, implementing, and analyzing multi-institutional cancer prevention, control, and screening/post-treatment surveillance clinical trials, quality-of-life studies embedded within treatment and imaging clinical trials and studies on cancer care delivery. Integration of individual functional components and their ability to interact with other NCORP awardees is particularly important.

2.1.1 Overall Impact - Overall

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the proposed NCORP Research Base to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the proposed NCORP Research Base).

2.1.2 Scored Review Criteria – Overall

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a proposed NCORP Research Base that by its nature is not innovative may be essential to advance a field.

Significance

Does the proposed NCORP Research Base address an important problem or a critical barrier to progress in the field? If the aims of the proposed NCORP Research Base are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

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Are the PD(s)/PI(s), collaborators, and other researchers well suited to the proposed NCORP Research Base and its research strategy? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Specific to this FOA: How well can the PD(s)/PI(s) and the entire applicant team provide scientific leadership for multi-institutional cancer prevention, control, and screening/post-treatment surveillance clinical trials? Will these investigators be able to work as a cohesive research team to efficiently and expeditiously develop and conduct NCORP clinical trials? Is the research experience and qualifications of the leadership and scientific committee members appropriate and sufficient for the focus of each committee? Does the team of cancer care delivery investigators assembled by the applicant have sufficient capabilities and experience in developing, conducting, and analyzing multi-institutional cancer care delivery research? Will investigators be able to work as a cohesive team within and with other NCORP research bases to efficiently develop and conduct NCORP cancer care delivery research? If the investigator team needs to be strengthened in any specific area, are there appropriate recruitment plans outlined?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the proposed NCORP Research Base? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects

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be managed?

If the NCORP Research Base involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the clinical research conducted by the NCORP Research Base benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Scored Review Criteria

In addition to the above review criteria, the following criteria will be applied to applications in the determination of scientific merit and the impact/priority score. Reviewers will consider each of the additional review criteria below in the determination of scientific merit, and give a separate score for each.

A. Cancer Prevention, Control and Screening Trial Development Program

B. Statistical Analysis/Data Management for Cancer Prevention, Control and Screening Trials

C. Cancer Care Delivery Research Program

D. Operational Management

E. Collaboration & NCORP Collective Management

Reviewers will consider each of the additional review criteria below in the determination of scientific merit, and give a separate score for each.

2.1.3 A. Cancer Prevention, Control, and Screening/Post-treatment Surveillance Clinical Trial Development Program

(Note: The entire Criterion A will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately.)

Research Priorities and Directions: How well do the applicant's chosen research areas and priorities reflect an integrated scientific approach to cancer prevention, control, and screening clinical trials including health-related quality-of-life studies embedded in treatment and/or imaging clinical trials? Do the research priorities

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address important unmet clinical needs? Do the research priorities incorporate disparities questions in diseases for which there are disproportionate burdens?

Quality of Clinical Trials: What is the overall quality of the clinical trials with the stated research (completed, ongoing, in development, or proposed)? Does the applicant team have effective mechanisms for promoting timely presentation and publications of the results of clinical trials and sub-studies? How adequate are the plans for the mentoring and training new and junior investigators in terms of leadership skills relevant to clinical trials?

Community Site Engagement: Are the plans for engaging NCORP Community Sites and Minority/Underserved Community Sites in the design and conduct of clinical trials likely to be effective and sufficient?

Accrual: Are the plans for recruitment and retention of study participants well conceived and realistic in terms of accrual goals and timeliness? How good are the applicants' systems/procedures to rapidly assess and monitor accrual and implement appropriate corrective actions if accrual is lagging?

2.1.4 B. Statistical Analysis and Data Management for Cancer Prevention, Control, and Screening/Post-treatment Surveillance Clinical trials

(Note: The entire Criterion B will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately.)

Statistical Analysis Program. Do the proposed plans demonstrate sufficient understanding of the design and analysis of multi-institutional cancer prevention, control, and screening clinical trials, including observational and longitudinal studies? Are the plans for final study analyses adequate to facilitate timely publication of study results?

Data Management. How well does the applicant define policies and procedures for data management of the cancer prevention, control, and screening clinical trials? How robust are the data management and study monitoring practices for individual institutions/sites and investigators?

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2.1.5 C. Cancer Care Delivery Research Program

(**Note:** The entire Criterion C will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately.)

Research Priorities. How well do the proposed research priorities reflect an integrated scientific approach to cancer care delivery research? How well does the proposed program address health disparity issues and studies involving minority/underserved patient populations? Are the proposed scientific committee(s) appropriate for the initiation of a cancer care delivery research agenda focused on multi-institutional community based studies? How adequate are the plans for the mentoring and training new and junior investigators in terms of leadership skills relevant to cancer care delivery research?

Statistical Analysis/Informatics Support. Do the proposed plans demonstrate sufficient understanding of design and analysis of multi-institutional observational and interventional cancer care delivery research? Is the approach for developing a working knowledge of the strengths and weaknesses of the data structures of inpatient/ambulatory data systems in the community setting well-conceived?

Data Management. How robust are the data management and study monitoring practices of the proposed Research Base for cancer care delivery for data provided by NCORP Community Sites and Minority/Underserved Sites? How sufficient are the available information technology resources in terms of securing support for central storage, security, analysis and retrieval of data?

Community Site Engagement. Are the plans for engaging NCORP Community Sites and Minority/Underserved Community Sites in the design and conduct of studies on cancer care delivery likely to be effective and sufficient?

D. Operational Management

(**Note:** The entire Criterion D will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately.)

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Governance and Operations. Is the organizational structure and the proposed governance and decision-making processes and interactions among the members of the leadership team adequate for achieving effective scientific design and conduct of clinical trials and studies on cancer care delivery? Are the proposed leadership succession plans (including limits for specific leadership functions) clearly defined and appropriate? If the application includes multiple PD(s)/PI(s), is it clear how activities and responsibilities will be carried out among the multiple PD(s)/PI(s) and is the delineation of responsibilities appropriate? Are the policies and procedures for affiliation of NCORP Community Sites, Minority/Underserved Community Sites and other organizations clear and appropriate? Are the operational practices/procedures and tracking of performance for protocol development and data collections appropriate?

Study Monitoring/Quality Control. How robust are the applicant's policies and procedures for study monitoring, data quality control, and accuracy verification, including auditing? How comprehensive and appropriate are the applicant's methods for active study monitoring, including procedures for accrual and biospecimen collection tracking, assessing participant eligibility and evaluability, ensuring timely medical review and assessment of participant data, monitoring of data quality and timeliness, and resolving issues? Are there clear guidelines for institutions/sites related to data timeliness and metrics for data quality? Are there clear guidelines on timely reporting by the Research Base to the institutions/sites of their performance relative to these guidelines? Does the applicant have a strong record of data quality and timeliness?

Standard Tools and Compliance. How extensive and appropriate is the applicants' utilization of standard NCI-supported tools for clinical trials? Are the applicant's policies and procedures adequate for assuring compliance with all the applicable regulations? How well do the proposed policies and procedures adhere to good practices for conduct of research?

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2.1.7 E. Collaboration & Participation in NCORP Collective Management

(**Note:** The entire Criterion E will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately.)

Research Collaborations. How useful will be the identified research collaborations for advancing the development of cancer prevention, control, and screening/post-treatment surveillance clinical trials and cancer care delivery research?

2.2 NCORP Community Site Review Criteria

Only the review criteria described below (and the Additional Review Criteria – Overall listed in Part 2 – Section III.B.3.) will be considered in the review process. As part of the [NIH mission](#), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

The emphasis of this FOA is on the ability of the proposed Community Site to recruit, enroll, and retain participants in multi-institutional cancer prevention, control, and screening/post-treatment surveillance clinical trials, quality-of-life studies embedded within treatment and imaging clinical trials and studies on cancer care delivery. Proper affiliation and meaningful contributions to the studies led by NCORP Research Base are also essential.

2.2.1 Overall Impact - Overall

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the proposed NCORP Community Site to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the proposed NCORP Community Site).

2.2.2 Scored Review Criteria – Overall

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a research infrastructure such as an NCORP Community Site that

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by its nature is not innovative may be essential to advance a field.

Significance

Does the NCORP Community Site address an important problem or a critical barrier to progress in the field? If the aims of the NCORP Community Site are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the NCORP Community Site? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Specific to this FOA: Are the qualifications, training, and experience of the PD/PI or the multiple PD/PIs/PDs (if applicable) appropriate for organizing and managing a community oncology research program that includes accrual to NCI-approved cancer prevention, control, screening/post-treatment surveillance, treatment and imaging clinical trials and cancer care delivery research? How experienced are PDs/PIs and other senior investigators in terms of leadership roles in the community or nationally in the areas that may enhance the NCORP Community Site and/or the research agenda of the affiliated Research Bases? How effectively has the applicant assembled a multidisciplinary oncology team for implementing a clinical trials agenda? Has (have) the component(s) proposed for participation in cancer care delivery research assembled a committed team for implementation of cancer care delivery research?

Innovation

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Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the NCORP Community Site? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the NCORP Community Site involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Scored Review Criteria

In addition to the above review criteria, the following criteria will be applied to applications in the determination of scientific merit and the impact/priority score. Reviewers will consider each of the additional review criteria below in the determination of scientific merit, and give a separate score for each.

- A. Organization and Structure
- B. Clinical Trials Research Program
- C. Cancer Care Delivery Research Program
- D. Operations/Data Management Core

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2.2.3 A. Organization and Structure

(Note: The entire Criterion A will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately).

Organizational Structure. How appropriate is the planned organizational structure to accomplish the proposed research activities?

Catchment Area. How complete is the information provided on the catchment area (e.g., geography, population, number of components)? Is the patient and provider pool large enough to ensure that the program will be able to meet or exceed the accrual requirements?

Clinical Practice Structure and Partnerships. Is the clinical practice structure appropriate in terms of the types and sizes of components (e.g., outpatient/inpatient practices, hospitals/clinics/cancer centers) and the number of participating oncologists, primary care and other providers? In particular, is this structure adequate to support accrual goals and the conduct of cancer care delivery research?

Institutional Commitment and Facilities. How convincing are the supporting documents for institutional commitment from the components? Are the available facilities and resources, including laboratories, in-patient and outpatient resources, cancer registries, and space for administrative activities adequate to support the proposed research activities?

2.2.4 B. Scored Review Criteria – Clinical Trials Research Program

(Note: The entire Criterion B will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately).

Experience. How successful has the applicant team been over the past 5 years in meeting or exceeding the minimum annual accrual goals for their clinical trials? How successful has the applicant been over the past 5 years in contributing to the research agenda of affiliated Research Bases and Cooperative Groups, if applicable?

Research Priorities. Are the applicant's priorities for implementing NCI-approved cancer clinical trials well

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thought out and appropriate for the applicant's organizational structure and capacity?
Does the applicant have a well-reasoned approach to facilitating understanding and adoption by community-based physicians and patients of genomic medicine and targeted cancer agents?
Are the recruitment, retention, and outreach plans for clinical trials described likely to be effective?

Research Base Affiliations. Are the current or proposed affiliations consistent with the rationale provided in the application? How likely is the applicant to contribute to the scientific agenda of its affiliated Research Bases over the next project period, including participation in scientific or community liaison committees; serving as Chair(s) on cancer clinical trials; authorship of joint publications, etc.?

Accrual. Are the proposed participant accrual plans matching the history of accrual by the applicant team, the overall size of the applicant and its components and the catchment area served? What is the likelihood that the applicants will be able to achieve the required minimal or exceed the number of 80 accruals per year over the proposed project period?

2.2.6 C. Scored Review Criteria – Cancer Care Delivery Research Program

(Note: The entire Criterion D will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately).

Experience and Research Priorities. How strong are the applicants' capabilities in the proposed areas of focus for cancer care delivery research? Are the study categories proposed by the applicant appropriate for the experience and capabilities of the Site component(s) designated for participation in cancer care delivery research?

2.2.7 D. Scored Review Criteria - Operations/Data Management Core

(Note: The entire Criterion E will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately).

Are the processes for ensuring compliance with regulations for IRB approval and informed consent (compliance with 45 CFR 46) related to research

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involving human subjects adequate? Do the applicants use (or plan to use) optimally the available relevant central and local resources? Are the procedures for investigational drug management in compliance with NCI and FDA requirements?

Are the procedures and workflow processes for activating clinical trials and studies on cancer care delivery as well as for recruiting, enrolling, and monitoring patients/participants clearly defined and adequate? Are the plans for communication among physicians and components and the incentives for participation in clinical trial and cancer care delivery research well-reasoned?

Do the data management procedures appear to be adequately robust for all the proposed activities? Is the internal quality assurance plan/program clearly outlined and robust enough?

Audit Performance. Do the clinical trial summary audit results confirm adequate performance?

2.3 NCORP Community Minority/Underserved Site Review Criteria

Only the review criteria described below (and the Additional Review Criteria – Overall listed in Part 2 – Section III.B.3.) will be considered in the review process. As part of the [NIH mission](#), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

The emphasis of this FOA is on the ability of the proposed Minority/Underserved Community Site to recruit, enroll, and retain participants in multi-institutional cancer prevention, control, and screening/post-treatment surveillance clinical trials, quality-of-life studies embedded within treatment and imaging clinical trials and studies on cancer care delivery. Essential for the proposed sites is the ability to engage patients/participants from minority and underserved (e.g., rural) populations. Proper affiliation and meaningful contributions to the studies led by NCORP Research Base are also essential.

2.3.1 Overall Impact - Overall

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the proposed NCORP Minority/Underserved Community Site to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for

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the proposed NCORP Minority/Underserved Community Site).

2.3.2 *Scored Review Criteria – Overall*

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a proposed NCORP Community Minority/Underserved Site that by its nature is not innovative may be essential to advance a field.

Significance

Does the NCORP Minority/Underserved Community Site address an important problem or a critical barrier to progress in the field? If the aims of the NCORP Minority/Underserved Community Site are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the NCORP Minority/Underserved Community Site? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Specific to this FOA: Are the qualifications, training, and experience of the PD/PI or the multiple PD/PIs/PDs (if applicable) appropriate for organizing and managing a community oncology research program that includes accrual to NCI-approved cancer prevention, control, screening/post-treatment surveillance, treatment, and imaging clinical trials and cancer care delivery? Have other Key/Senior personnel taken on leadership roles in the community or nationally that contribute to the success of the NCORP Minority/Underserved Community Site and/or the research agenda of the affiliated Research Bases? How effectively has the applicant

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assembled a multidisciplinary oncology team for implementing a clinical trials agenda? Has (have) the component(s) proposed for participation in cancer care delivery research assembled a committed team for implementation of cancer care delivery research ?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the NCORP Minority/Underserved Community Site? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the NCORP Minority/Underserved Community Site involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Scored Review Criteria

In addition to the above review criteria, the following criteria will be applied to applications in the determination of scientific merit and the impact/priority score. Reviewers will consider each of the additional review criteria below in the determination of scientific merit, and give a separate score for each.

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- A. Organization and Structure
- B. Clinical Trials Research Program
- C. Cancer Care Delivery Research Program
- D. Operations/Data Management Core

2.3.3 A. *Organization and Structure*

(Note: The entire Criterion A will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately).

Organizational Structure. How appropriate is the planned organizational structure to accomplish the proposed research activities?

Catchment Area. How complete is the information provided on the catchment area (e.g., geography, population, number of components)? Is the patient and provider pool large enough to ensure that the program will be able to meet or exceed the accrual requirements for the Minority/Underserved Community Site?

Clinical Practice Structure and Partnerships. Is the clinical practice structure appropriate in terms of the types and sizes of component sites (e.g., outpatient/inpatient practices, hospitals/clinics/cancer centers) and the number of participating oncologists, primary care and other providers? In particular, is this structure adequate to support accrual goals and the conduct of cancer care delivery research ?

Access to Minority and Underserved Populations. Does the applicant team have a sufficient track record of serving minority and underserved populations? Are the patterns of care for minorities and underserved populations in the communities served rigorously described and properly substantiated by data provided?

Institutional Commitment and Facilities. How convincing are the supporting documents for institutional commitment from the Site components? Are the available facilities and resources, including laboratories, in-patient and outpatient resources, cancer registries, and space for administrative activities adequate to support the proposed research activities?

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2.3.4 B. Scored Review Criteria - Clinical Trials Research Program

(Note: The entire Criterion C will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately).

Experience. How successful has the applicant been over the past 5 years in meeting or exceeding the minimum annual accrual goals for their clinical trials? How successful has the applicant been over the past 5 years in contributing to the research agenda of affiliated Research Bases and Cooperative Groups?

Research Priorities. Are the applicant's priorities for implementing NCI-approved cancer clinical trials well thought out and appropriate for the applicant's organizational structure and capacity? Does the applicant have a well-reasoned approach to facilitating an understanding and adoption by community-based physicians and patients of genomic medicine and targeted cancer agents? Are the recruitment, retention and outreach plans for clinical trials described likely to be effective?

Research Base Affiliations. Are the current or proposed affiliations consistent with the rationale provided in the application? How likely is the applicant to contribute to the scientific agenda of its affiliated Research Bases over the next project period, including participation in scientific, community liaison, or disparities/underserved committees; serving as Chair(s) on cancer clinical trials; authorship of joint publications, etc.?

Accrual. Are the proposed participant accrual plans matching the history of accrual by the applicant team, the overall size of the applicant and its component sites and the catchment area served? What is the likelihood that the applicants will be able to achieve the required minimal or exceed the number of 80 accruals per year over the proposed project period?

2.3.5 C. Scored Review Criteria – Cancer Care Delivery Research Program

(Note: The entire Criterion D will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately).

Experience and Research Priorities. How strong are the applicants' capabilities in the proposed areas of focus

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for cancer care delivery research? Are the study categories proposed by the applicant appropriate for the experience and capabilities of the Site component(s) designated for participation in cancer care delivery research?

2.3.6 E. *Scored Review Criteria - Operations/Data Management Core*

(**Note:** The entire Criterion E will receive one individual score; the subcategories and aspects listed will be assessed but not scored separately).

Are the processes for ensuring compliance with regulations for IRB approval and informed consent (compliance with 45 CFR 46) related to research involving human subjects adequate? Do the applicants use (or plan to use) optimally the available relevant central and local resources? Are the procedures for investigational drug management in compliance with NCI and FDA requirements?

Are the procedures and workflow processes for activating clinical trials and studies on cancer care delivery as well as for recruiting, enrolling, and monitoring patients/participants clearly defined and adequate? Are the plans for communication among physicians and components and the incentives for participation in clinical trial and cancer care delivery research well-reasoned?

Do the data management procedures appear to be adequately robust for all the proposed activities? Is the internal quality assurance plan/program clearly outlined and robust enough?

Audit Performance. Do the clinical trial summary audit results confirm adequate performance?

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3. Additional Review Criteria – Overall – for All Key Components of NCORP

As applicable for the clinical research that the applicant for a key component under NCORP has proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

3.1 *Protections of Human Subjects*

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

3.2 *Inclusion of Women, Minorities, and Children*

When the proposed key component of NCORP involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

3.3 *Vertebrate Animals*

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section](#).

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3.4 Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

3.5 Resubmissions, Renewals, and Revisions

Resubmissions, renewals, and revisions are not applicable at the current time for NCORP Program.

4. Additional Review Considerations – Overall – for All Key Components of NCORP (except for Resource Sharing Plans)

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

4.1 Applications from Foreign Organizations

Applications from foreign organizations are not permitted for the following key components of NCORP:

- Research Bases
- Community Sites
- Minority/Underserved Community Sites

4.2 Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

4.3 Resource Sharing Plans – NCORP Research Bases only

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) [Data Sharing Plan](#); 2) [Sharing Model Organisms](#), if applicable, and 3) [Genome Wide Association Studies \(GWAS\)](#).

Applicants should review the information in the associated Funding Opportunity Announcement for the key component of the NCOR Program as to what needs to be submitted with respect to Resource Sharing Plans. However, final approval of all Resource Sharing Plans is determined by NCI/DCP staff prior to the start date of the award:

4.4 Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

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C. Review Scoring

All scored components of the applications under NCORP (i.e., the General Core Review Criteria Category and the Scored Additional Specific Review Criteria Categories) are scored numerically using the 9-point scale (1 =exceptional; 9=poor) scoring scale. Any of these components can be rated Not Recommended for Further Consideration (NRFC) if the component lacks significant and substantial merit.

For each discussed application, a final numerical impact/priority score from 1 (exceptional) to 9 (poor) will be given by each eligible SEP member (those without conflicts of interest). Each reviewer's overall impact/priority score will reflect his/her evaluation of the likelihood that the overall application will have a sustained powerful impact on clinical research conducted by the NCORP.

Reviewers will focus on the scored categories, excluding any components not recommended for further consideration, in assigning the final overall impact/priority score. However, inclusion of components of poor quality will be considered evidence of poor judgment by the Principal Investigator(s) for the application. Reviewers do not have the option to select only the better components of an application to improve the overall impact/priority score.

If an application has many major weaknesses and therefore is likely to have low impact relative to all other applications normally received by the NCI, the review panel may choose to expedite the discussion/ or to not discuss the application. An entire application can be not recommended for further consideration if it lacks significant and substantial merit or presents serious ethical problems in the protection of human subjects from research risks, use of vertebrate animals, biohazards, and/or select agents.

D. Review Summary Statement

The summary statement is the official record of the review of the application. The summary statement includes administrative information about the application, the final overall impact/priority score if the application was discussed, codes for the committee's determination of the adequacy of protections for human subjects and animal welfare (if applicable) and several narrative sections conveying the opinions and recommendations of the reviewers assigned to the application. The summary statement for applications discussed during the review meeting will include a Resume and Summary of Discussion, an Overall Critique section summarizing the strengths and weaknesses of the Overall Program, summary paragraphs listing the strengths and weaknesses and the final impact score/rating of each scored review criteria category, and resumes for human subjects, vertebrate animals (if applicable) and other additional review criteria, which are prepared by the SRO.

The summary statement will also contain individual reviewers' criteria category scores along with the essentially unedited critiques and other components of the application. Applicants should note that some reviewers may not have updated their critiques after the review meeting to reflect their

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final opinions after the discussion. However, the overall Resume and Summary of Discussion, the Overall Critique section, and the summary paragraphs prepared by the SRO will reflect the final opinions of the review committee.

For applications that are not discussed during the meeting, the summary statement may not include an Overall Critique section, but it will include the individual criteria category scores along with the essentially unedited critiques and other components of the application.

The SRO prepares the summary statements as soon as possible after each review meeting. Each summary statement is released as soon as it is completed. Depending on the number of applications that were reviewed in each SEP, summary statements are usually completed within 6 weeks after the review meeting. The Principal Investigator(s) can access the summary statement through the NIH eRA Commons (<http://commons.era.nih.gov>) after it has been finalized and released by the SRO.

The summary statement will be transmitted to the National Cancer Advisory Board (NCAB) for second level peer review, to the NCI official file and to the appropriate NCI/DCP staff.

E. Awards

The award and administration of key components of NCORP are subject to the same policies and procedures as other research grants. These policies and cost principles are set forth in the current PHS Grants Policy Statement, other NIH and NCI issuances and Federal legislation and regulations.

Following review by the NCAB, scored applications are considered for funding by the NCI. NCI/DCP program staff may administratively delete funding or reduce the duration of support for components of the key component that are judged by peer review to be less meritorious and/or nonessential to the conduct of the component.

F. Questions on Review Process

Questions related to the review of all NCORP Program key components review may be directed to:

Referral Officer
Division of Extramural Activities (DEA)
National Cancer Institute (NCI)
9609 Medical Center Drive, Room
Bethesda, MD 20892 (for U.S. Postal Service express or regular mail)
Rockville, MD 20850 (for non-USPS delivery)
Telephone: (240
FAX: (301) 402- 0275
Email: ncirefof@dea.nci.nih.gov

Part 3: Guidelines for Submission of Continuing Applications (Annual Progress Reports)

I. Application Submission Instructions

The following sections include instructions on the types of information that should be included in the non-competing continuation applications (Type 5 Applications) submitted by each of the 3 key components of NCORP, i.e., the Annual Progress Reports. Applicants should consult the PHS 2590 at: <http://grants.nih.gov/grants/funding/2590/2590.htm> for up-to-date information on NIH requirements for completing the annual Progress Report or Type 5 Application. The annual Progress Report (Type 5 Application) is required for every year of award, including the year in which a competing continuation application (Type 2 Application) may be submitted in the future under the Program.

The Progress Report should contain the basic information needed to allow the responsible NCORP Director and Co-Program Directorss to monitor the progress and performance of all the key components.

The submission procedures for non-competing continuation applications are described below.

SENDING A NON-COMPETING APPLICATION TO THE NIH:

Two (2) months before the start of the budget period, submit the original application, signed by the Principal Investigator(s) and the authorized business official, and one copy of the application to the address below, according to the instructions in the PHS 2590.

Division of Extramural Activities Support, OER
National Institutes of Health
6705 Rockledge Drive, Room 2207, MSC 7987
Bethesda, MD 20892-7987 (for U.S. Postal Service [USPS] Express or Regular mail)
Bethesda, MD 20817 (for Express/courier Non-USPS Service)
Phone: 301-594-6584

NOTE: All applications and other deliveries must be delivered either via courier or via USPS. Applications delivered by individuals will not be accepted. C.O.D. applications will not be accepted. This policy does not apply to courier deliveries (e.g., FedEx, DHL, etc.).

The procedures for non-competing continuation applications for all key components of NCORP are the same. The information provided in the application or annual report, however, should be focused on the specific activities of these entities (e.g., collection, transfer, and assessment of data collected or therapy delivered on a clinical trial and/or participation in trials rather than on the development of a specific scientific agenda and series of clinical trials).

Part 3: Guidelines for Submission of Continuing Applications (Annual Progress Reports)

II. Non-Competing Continuation Applications Format and Budget Requests: *A. Applications for all Key Components of NCORP*

II. Non-Competing Continuation Applications Format and Budget Requests

The information included in a non-competing continuation application (also called an annual progress reports or Type 5 Application) should be provided in formats similar to the ones presented in this Part of the Guidelines and should follow the requirements of the PHS2590 available at:
<http://grants.nih.gov/grants/funding/2590/2590.htm>.

Providing the information in a standard format will allow both the key component of NCORP and the responsible NCORP Director and Co-Program Directors to evaluate the progress of the key component more easily and to identify areas that need attention. The format may be varied somewhat, depending on the key component submitting the application. The non-competing continuation application must specify the 12-month period for which data are being reported, and this same 12-month period should be used for all information presented.

It is anticipated that additional instructions/modification as to what information should be included in the annual progress report may be given to awardees of all the key components of NCORP by the NCORP Director prior to submission of the first annual progress report, especially with respect to streamlining the report.

A. Applications for all Key Components of NCORP

1. Research Plan (Annual Progress Report – Type 5 Application)

The Research Plan for each Type 5 application should follow the requirements of the PHS2590. In all cases, brief and concise descriptions in the research plan of annual progress are encouraged. Sections 1.1 and 1.2, accrual and clinical trial performance and Section 1.3, clinical trial development described below apply only to the NCORP Research Bases' annual progress reports.

1.1 Accrual Performance & Accrual by Gender and Ethnicity/Race

NCORP Research Bases should provide a summary table that lists the number of patients accrued during the current funding period (i.e., the three [3] most recently completed quarters during the funding period plus a projection for the current fourth quarter) with the exact calendar dates/time-periods used to provide the actual and projected accrual noted at the top of the table. Accrual for all studies (prevention, control and screening/post-treatment surveillance trials) and per patient biospecimen collection on trials that were open during the annual project period should be reported summarized by major disease category and trial phase. A similar report summing accrual across all disease areas should also be provided. Total accrual provided by the NCORP Research Base for all its member institutions/sites) broken down by sex/gender and ethnicity/race for all accrual across all NCORP trials (excluding accrual of patients to quality of

Part 3: Guidelines for Submission of Continuing Applications (Annual Progress Reports)

II. Non-Competing Continuation Applications Format and Budget Requests: ***A. Applications for*** all
Key Components of NCORP

life sub-studies to treatment trials) should also be presented using the standard Inclusion Enrollment Report format provided in the PHS2590. This table should be modified to show sex/gender and ethnicity/race breakdown in accrual for the previous 3 years (if applicable) in addition to the current funding period summarized by major disease category only. A summary table for accrual across all diseases should also be provided. Distribution of subjects should NOT be provided by individual study or trial phase.

Part 3: Guidelines for Submission of Continuing Applications (Annual Progress Reports)

II. Non-Competing Continuation Applications Format and Budget Requests: **A. Applications for all Key Components of NCORP**

Summary Accrual Table for ALL Studies by a NCORP Research Base by Annual Funding Period - (Annual Grant Year)

Disease Area: _____ (AND PROVIDE REPORT SUMMARIZING ACCRUAL ACROSS ALL DISEASE AREAS)

Time Period (Calendar Dates) for Actual Accrual:

Time Period (Calendar Dates) for Projected Accrual:

TYPE OF STUDY	PILOT Prevention , Control and Screening/ Post- Treatment Surveillanc e Trials	PHASE 1 Prevention, Control and Screening/ Post- Treatment Surveillanc e Trials	PHASE 2 Prevention , Control and Screening/ Post- Treatment Surveillanc e Trials	PHASE 3 Prevention , Control and Screening/ Post- Treatment Surveillanc e Trials	Other Per Patient Special or Biospecim en Collection	ALL Prevention , Control and Screening/ Post- Treatment Surveillanc e Studies
Patients Enrolled on All NCORP Studies Led by NCORP Research Base (i.e., applicant) (current period) Actual (projected) Accrual - Credited to Group Actual (projected) Accrual - Credited to Other Groups ===== ===== Patients Enrolled on All NCORP Studies NOT Led by NCORP Research Base (i.e., applicant) (current period): Actual (projected) Accrual - Credited to Group						

- Accrual figures should include both eligible and ineligible patients. .
- Pilot studies refer to studies testing the feasibility of administration of the therapeutic intervention/approach and any other trials that do not fit into the other categories listed.

Part 3: Guidelines for Submission of Continuing Applications (Annual Progress Reports)

II. Non-Competing Continuation Applications Format and Budget Requests: ***A. Applications for*** all
Key Components of NCORP

- Actual data should usually be available for the 3 most recently completed quarters of the annual grant year (funding period) and data should be projected for the current quarter; however, the applicant should list the specific calendar dates for actual data and the specific calendar dates for the projected data supplied in the heading information for the table so that it is clear to reviewers what is being presented. If an applicant does not make projections by certain categories (e.g., the applicant projects data only by “all studies” not by specific categories of studies, the applicant should designate that this information is “Not Available” in the appropriate location in the table. The designation of “Not Applicable” should be used to indicate that that category is not appropriate for the applicant and no data will be forthcoming for that category.

Part 3: Guidelines for Submission of Continuing Applications (Annual Progress Reports)

II. Non-Competing Continuation Applications Format and Budget Requests: **A. Applications for all Key Components of NCORP**

Summary Accrual Table for ALL HRQOL Sub-studies to Treatment Trials by a NCORP Research Base Annual Funding Period - (Annual Grant Year)

Disease Area: _____ (AND PROVIDE REPORT SUMMARIZING ACCRUAL ACROSS ALL DISEASE AREAS)

Time Period (Calendar Dates) for Actual Accrual:

Time Period (Calendar Dates) for Projected Accrual:

HRQOL Sub-studies to NCTN Treatment Trials	NCORP Community Site	NCORP Minority/Underserved Community Site	Other Member Institutions (including LAPS)	Totals

Accruals

- Accrual figures should include both eligible and ineligible patients. .
- Actual data should usually be available for the 3 most recently completed quarters of the annual grant year (funding period) and data should be projected for the current quarter; however, the applicant should list the specific calendar dates for actual data and the specific calendar dates for the projected data supplied in the heading information for the table

Part 3: Guidelines for Submission of Continuing Applications (Annual Progress Reports)

II. Non-Competing Continuation Applications Format and Budget Requests: *A. Applications for all Key Components of NCORP*

1.2 Clinical Trial Performance

NCORP Research Bases should also summarize the timeliness of AdEERS reports submission, the date of the last audit for institutional members (including NCORP Community and Minority/Underserved Community Sites), compliance with specimen submission, etc. in the annual report.

The NCI-Guidelines for Onsite Monitoring of Clinical Trials for Cooperative Groups, CCOP Research Bases, and the Cancer Trials Support Unit (CTSU) require all institutions to be audited at least once every 36 months. In order for NCI to review the NCORP Research Base's compliance with this requirement, each NCORP Research Base should conduct an annual review of all audits performed and provide in the non-competing continuation application an accounting similar to the table provided for new applications. Any significant audit problems, as defined in the Clinical Trials Monitoring Branch Guidelines for Onsite Auditing, encountered during the preceding year should be fully described and the corrective action(s) taken explained for any NCORP Research Base's institutional/site members (including NCORP Community and Minority/Underserved Community Sites).

1.3 Timelines for Protocol Development, Trial Activation, and Trial Completion

The annual progress report should list protocol development activities during the current funding period for the NCORP Research Base, in terms of submitted and approved Concepts, submitted and approved protocols, activated and completed trials with associated timelines. This table should be organized by major disease category and then by trial phase.

1.4 Progress & Summary of Research Accomplishments of Key Components of NCTN Program

The annual progress report for each key component of NCORP (i.e., Research Bases, Community Sites and Minority/Underserved Community Sites) should report on the component's progress regarding the goals and activities outlined in the research plan of the corresponding Type 1 application (or Type 2 application, if applicable in the future). This should include information on how the key component has contributed to the goals of NCORP with emphasis on what the key component has accomplished in the current funding period.

The application should provide a brief, narrative description of the contributions of the key component to NCORP clinical trials and research goals and other NCORP Program activities and initiatives, including important collaborations, during the current funding period. This summary narrative should be adequate to convey the important facets of the activity and any significant findings (e.g., patients

Part 3: Guidelines for Submission of Continuing Applications (Annual Progress Reports)

II. Non-Competing Continuation Applications Format and Budget Requests: *A. Applications for all Key Components of NCORP*

accrued, open dose level, important toxicities observed, pharmacokinetic findings, anti-tumor activity observed, scientific leadership on new trials, translational science advances, etc.).

The annual progress report should list the titles and complete references of all publications not previously reported. This includes manuscripts submitted or accepted for publication. Only those publications resulting directly from activities of the key component of NCORP funded by the Cooperative Agreement should be reported.

1.5 Key Personnel and Training on Human Subjects Protection for New Key Personnel

Each key component of NCORP should submit a list of key personnel, highlighting any changes. In addition, the key component should indicate the type of training course/program on human subjects protection completed by each new key personnel member.

2. Budget (Annual Progress Report – Type 5 Application)

2.1 General Budget Information

The budget included in the non-competing application should be similar to that provided in the new application, except it is limited to the upcoming 12-month funding period. A Common Budget Outline, similar to that required for a new application may also be requested by the NCI/DCP on an ad hoc basis with the Annual Progress Report, but this is not expected to be provided annually.

2.2 Non-Competing Budget Adjustments

General comments: Out-year budget commitments, as reflected in each Notice of Grant Award, are based upon the funding level for the competing year; however, funding levels can be increased or reduced because of increments or decrements in performance on the part of the Cooperative Agreement awardee or a change in the funds available to the government for distribution.

Requests for the adjustments are initiated by the key component, and are based on such factors as increased or decreased level of activity at an institution. The effect of any such adjustment will be reflected in revised out-year commitments. Authority to effect an adjustment rests with NCI Grants Management Officer in the NCI Office of Grants Administration (OGA) on the recommendation of the NCORP Director. Funding adjustments are facilitated by the NCI/DCP Senior Program Specialist.

Process: Informal administrative discussions about a contemplated adjustments or carryover may take place between the NCI/DCP Senior Program Specialist and administrator for the key component of NCORP, and may be initiated by either party. The NCI/DCP Senior Program Specialist is responsible for providing an estimate of available budget for the Program as a whole and for the various key components for the Program,

Part 3: Guidelines for Submission of Continuing Applications (Annual Progress Reports)

II. Non-Competing Continuation Applications Format and Budget Requests: *B. Notification of International Involvement in Key Components of NCORP Program*

based on discussions with the NCORP Director. Similarly, the NCORP

Director and Co-Program Directors are typically in ongoing discussions with the key components of NCORP on their budgetary needs and scientific priorities.

Type 5 Applications are due at the NCI eight (8) weeks prior to the award date, so sufficient time should be allotted to permit timely receipt of applications in line with any request for redistribution or carryover. In connection with this time-line, it should be noted that OGA generally requires a formal, updated budget when changes of more than 25 per cent are requested.

2.3 Budget Adjustments by NCI/DCP for Key Components of NCORP

Adjustments may be made by NCI/DCP in the funding of the key component of NCORP at the time of a non-competing continuation award. Such adjustments provide the NCI with the ability to ensure that available funds are put to their best use. Authority to effect adjustments in funding rests with the NCORP Director, who works in conjunction with the NCI/DCP Senior Program Specialist.

Budget commitments for the non-competing years are based upon the funding level for the competing year. Increases or decreases in funding for any key component of NCORP may be made on the basis of changes in performance relative to that approved in the competing application or in the previous year. The actual monies awarded are always, of course, subject to the availability of funds. Thus, funding levels can be increased or reduced because of increments or decrements in performance on the part of the awardee, particularly with respect to funding restricted for use to cover data collection/management and biospecimen collection related to enrollment of patients on clinical trials and their follow-up and/or a change in the funds available to the government for distribution.

In particular, the NCORP Community and Minority/Underserved Sites will undergo assessment with possible decrement in funding after 3-years of performance based on the awardee's accrual to NCORP and NCTN trials.

B. Notification of International Involvement in Key Components of NCORP Program

The key component of NCORP must alert the NCI/DCP Senior Program Specialist for NCORP and to the Office of Grants Administration (OGA) when a non-competing application involves any new international (non-U.S.) component, regardless of whether the component receives federal funding under the awardee's grant. In such cases, advance clearance from the U.S. Department of State is required for each non-U.S. component prior to the start date of the award. The information required

Part 3: Guidelines for Submission of Continuing Applications (Annual Progress Reports)

II. Non-Competing Continuation Applications Format and Budget Requests: ***B. Notification of International Involvement in Key Components of NCORP Program***

by U.S. Department of State is listed below (this information should also include all non- U.S. subcontracts).

- Estimated annual Total Cost dollar award for the non- U.S. component
- Name, organization, city, and country of the International (non-U.S.) Principal or Collaborating Investigator(s)
- Biosketch and Curriculum Vitae (CV) for both the domestic Principal Investigator and the international Principal Investigator
- OHRP assurance number (i.e., Federal wide Assurance number) for the non-US component

In addition, for international sites collaborating with a U.S. NCORP Research Base on trials sponsored under the NCORP Program (regardless of whether the U.S. organization or the international organization is leading the trial and regardless of whether any funding is being provided), U.S. Department of State clearance is required for the non-U.S. country as clinical data is being passed between the U.S. organization supported under NCORP and the other country.

Part 4: Appendices

NCI/DCTD/DCP Policies for the NCTN/NCORP Programs (URLs to Websites): ***B. Notification of International Involvement in Key Components of NCORP Program***

Part 4: Appendices

I. NCI/DCTD/DCP Policies for the NCTN/NCORP Programs (URLs to Websites)

- A. NCI National Clinical Trials Network Program (NCTN) Guidelines
http://ctep.cancer.gov/investigatorResources/default.htm#guidelines_policies
- B. Investigator's Handbook (A Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by CTEP, DCTD, NCI)
http://ctep.cancer.gov/investigatorResources/investigators_handbook.htm
- C. NCI-CTMB Guidelines for Monitoring of Clinical Trials for Cooperative Groups, CCOP Research Bases, and the Cancer Trials Support Unit (CTSU)
http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_coop_ccop_ctsu.htm
- D. IP Option Policy:
http://ctep.cancer.gov/industryCollaborations2/default.htm#guidelines_for_collaborations
<http://ctep.cancer.gov/industryCollaborations2/default.htm>
- E. Operational Efficiency Working Group (OEWG) Policy and Timelines:
<http://ctep.cancer.gov/SpotlightOn/OEWG.htm>
- F. Policy on Contract Review
<http://ctep.cancer.gov/industryCollaborations2/guidelines.htm>
- G. (Under NCI Standard Protocol Language for Collaborative Agreements)
- H. Early Stopping Guidelines for Slowly-Accruing Phase 3 Studies
http://ctep.cancer.gov/protocolDevelopment/default.htm#cde_data_pol_cdus
- I. (Under CDE / Data policies / CDUS – Slow Accrual Guidelines for Phase 3 Trials)
- J. Adverse Event Expedited Reporting System (AdEERS)
http://ctep.cancer.gov/protocolDevelopment/electronic_applications/adeers.htm
http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf
- K. Information on Common Data Elements (CDE) Approved for Use in CTEP-sponsored Clinical Trials
<https://cabig.nci.nih.gov/community/concepts/caDSR/>
- L. NCI's Common Terminology Criteria for Adverse Events (CTCAE)
<http://ctep.cancer.gov/reporting/ctc.html>
- M. NCI Clinical Trials Cooperative Group Program Guidelines for the Development, Conduct and Analysis of Clinical Trials with International Collaborating Institutions (Under Guidelines & Policies)
http://ctep.cancer.gov/investigatorResources/default.htm#guidelines_policies
- N. CTEP Conflict of Interest Policy for Cooperative Group Phase 3 Clinical Trials (Under Guidelines and Policies)
http://ctep.cancer.gov/investigatorResources/default.htm#guidelines_policies

Part 4: Appendices

NCI/DCTD/DCP Policies for the NCTN/NCORP Programs (URLs to Websites): *B. Notification of International Involvement in Key Components of NCORP Program*

- O. NCI Templates for Simplified Model Informed Consent Documents for NCTN Trials
<http://cancer.gov/clinicaltrials/patientsafety/simplification-of-informed-consent-docs/page3>
- P. NCORP Organizational Change Guidelines
<http://prevention.cancer.gov/ncorp>

II. Suggested Formats - Tables for New Applications: NCORP Research Bases List of Tables with Suggested Formats

II. Suggested Formats - Tables for New Applications

Current and/or relevant information in the past 5 years should be used in the tables. Suggested reporting period over past 5 years for all tables requested for the application is June 1, 2008 thru May 31, 2013.

A. NCORP Research Bases List of Tables with Suggested Formats

NCORP Research Base applicants should include key leadership, scientific achievements, accrual and other information (e.g., operational efficiency timelines) from participation in the former NCI/DCP-sponsored CCOP Research Base Program. New applicants who did not participate in the former NCI/DCP-sponsored CCOP Research Base Program should provide accrual and other information from cancer clinical trials and cancer care delivery research studies supported by an equivalent organization that conducts such trials (not industry, investigator-initiated or early phase trials). Accrual tables are for cancer prevention, control, and screening clinical trials and cancer care delivery research studies only.

Table 1. Key Leadership Staffing As of Date of Application Preparation: MM/DD/YYYY

This table should reflect current positions in the applicant NCORP Research Base held by investigators with institutional affiliation as of the date this table was prepared for inclusion in the application. Please Note: Information pertaining to key positions held by NCORP Research Base investigators in NCI Scientific Steering Committees, Task Forces & working groups, NCI Central Institutional Review Board (CIRB), etc., should be provided in the text of "Collaboration & NCORP Collective Management" of the Research Plan for NCORP Research Bases (see page 18 on research plan & page 23 on review criteria).

Staffing Category for NCORP Research Base	Member Status	Member Name	Title	Institution	Length of Service in Position
Executive or Oversight Committee (All members should be listed)	Chair				
	Vice-Chair				
	Member				
	Member etc.				
Data and Safety Monitoring Board or Data Monitoring Committee (All members should be listed)	Chair				
	Vice-Chair				
	Member				
	Member etc.				

Part 4: Appendices

II. Suggested Formats - Tables for New Applications: NCORP Research Bases List of Tables with Suggested Formats

Scientific Committee #1 (List Chair and Vice-Chair(s) only)	Chair				
	Vice-Chair				
Scientific Committee #2 (List Chair and Vice-Chair(s) only)	Chair				
	Vice-Chair				
Administrative Committee #1 (List Chair and Vice-Chair(s) only)	Chair				
	Vice-Chair				
Administrative Committee #2 (List Chair and Vice-Chair(s) only)	Chair				
	Vice-Chair				

etc.

Table 2. Primary Scientific Achievements for Clinical Trials by Category from 6/1/08 – 5/31/13

Please Note: The primary scientific achievement refers to the Primary Endpoint(s) for the trial specified in the protocol document. Applicants should briefly explain in the narrative portion of the application the importance of the achievement regardless of whether the results were positive or negative as it is the importance of the achievement that is the focus of the table for reviewers, not the number of publications. Accrual figures should include eligible and ineligible patients. Screened patients refer to patients who are screened only for studies that have screening as a distinct part of the protocol. .

1) List clinical trials by category (i.e., Prevention trials followed by Control followed by Screening)

1) Trial Category	Trial Number & Brief Title	Trial Phase	Intervention: Experimental Agent, Regimen or Other Modality	Primary Endpoint Result - Indication	Year (Publication or FDA Indication or Other)	Manuscript or Abstract Reference	Date Trial Activation	Date Trial Closed to Accrual	Targeted Sample Size	Total Accrual
Prevention										

Part 4: Appendices

II. Suggested Formats - Tables for New Applications: NCORP Research Bases List of Tables with Suggested Formats

Control										
Screening										

Table 3a. Cancer Prevention, Control and Screening Concepts in Development

(Not yet submitted to NCI for review but has been through some portion of Research Base's internal review process)

- 1) List concepts by category (i.e., Prevention concepts followed by Control followed by Screening)

1) Concept Category	Concept Brief Title	Projected Concept Submission Date to NCI	Target Population	Primary Objective	Projected Duration of Study	Target Sample Size
Prevention						
Control						
Screening						

Table 3b. Cancer Prevention, Control and Screening Concepts Approved by NCI for Protocol Development

List only prevention, control and/or screening concepts approved by NCI since 2008.

- 1) List concepts by category (i.e., Prevention concepts followed by Control followed by Screening)

1) Concept	Concept Number	Projected Protocol	Projected Study	Target Sample	Projected Monthly	Estimated Annual Accrual
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II. Suggested Formats - Tables for New Applications: NCORP Research Bases List of Tables with Suggested Formats

Category	& Brief Title	Submission Date to NCI	Duration	Size	Accrual Rate	NCORP & MU NCORP	Member & Affiliate
Prevention							
Control							
Screening							
Total Estimated Accrual							

Table 3c. Cancer Prevention, Control and Screening Clinical Trials Approved by NCI but Not Yet Active

List only prevention, control and screening clinical trials approved by NCI 2008.

- 1) List clinical trials by category (i.e., Prevention trials followed by Control followed by Screening)

1) Clinical Trial Category	Trial Number & Brief Title	Trial Phase	Estimated Activation Date	Projected Study Duration	Target Sample Size	Projected Monthly Accrual Rate	Estimated Annual Accrual	
							NCORP & MU NCORP	Member & Affiliate
Prevention								
Control								
Screening								
Total Estimated Accrual								

Part 4: Appendices

II. Suggested Formats - Tables for New Applications: NCORP Research Bases List of Tables with Suggested Formats

Table 4a. Summary Accrual for Currently Open Trials Led by Applicant Research Base

Include only clinical trials open and are **still accruing patients** or that are temporarily closed to accrual. Accrual figures should include eligible and ineligible patients who have been enrolled in a trial. .

- 1) List clinical trials by category (i.e., Prevention trials followed by Control followed by Screening)

1) Clinical Trial Category	Trial Number & Brief Title	Trial Phase	Date Open for Patient Accrual	Trial Status (Open or temporarily closed to accrual)	Target Sample Size	Accrual to Date		% Projected Monthly Accrual Rate	Estimated Closure Date
						CCOP & MBCCOP	Member & Affiliate		
Prevention									
Control									
Screening									
Grand Total Accrual to Date									

Table 4b. Summary Accrual for Closed Trials Led by Applicant Research Base from 6/1/08 – 5/31/13

Include only clinical trials **closed to accrual** during previous 5 year period. Accrual figures should include eligible and ineligible patients who have been enrolled in a trial. .

- 1) List clinical trials by category (i.e., Prevention trials followed by Control followed by Screening)

1) Clinical Trial Category	Trial Number & Brief Title	Trial Phase	Date Open for Patient Accrual	Date Study Closed	Target Sample Size	Total Accrual		Comments
						CCOP & MBCCOP	Member &	

Part 4: Appendices

II. Suggested Formats - Tables for New Applications: NCORP Research Bases List of Tables with Suggested Formats

							Affiliate	
Prevention								
Control								
Screening								
Grand Total Accrual								

Table 5. Cancer Care Delivery Research Study Accomplishments

Include **closed and ongoing accrual** during previous 5 year period.

- 1) Indicate study type (e.g., observational, interventional, survey research)
- 2) Indicate data collection method (e.g., primary, secondary)

1) Study Type	2) Data Collection Method	Study Number & Brief Title	Target Sample Size	Total Accrual	Date Study Open for Accrual	Date Study Closed (if applicable)	Multi- Site (Y/ N)	Publication Submission Date	Publication Date	Publication Reference	Comments
Grand Total Accrual											

**Table 6. Summary of General Data Timeliness for Open Cancer Prevention, Control and Screening Clinical Trials Led by Applicant Research Base
6/1/08 – 5/31/13**

Include only clinical trials open over past 5 years. Can select major Case Report Form (CRF) categories that believe represent a measure of submission of general data timeliness to its trials (columns are examples only).

Participating Site Member	Year	Accrual	% Eligible	Eligibility CRF	Treatment Cycle %	Off Study CRF
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Part 4: Appendices

II. Suggested Formats - Tables for New Applications: *NCORP Research Bases List of Tables with Suggested Formats*

Category			Patients	Reporting % Timeliness	Timeliness	Reporting % Timeliness
Main Members	1					
	2					
	3					
	4					
	5					
Affiliates of Main Members	1					
	2					
	3					
	4					
	5					
CCOPs & MBCCOPs	1					
	2					
	3					
	4					
	5					
CCOP & MBCCOP Components	1					
	2					
	3					
	4					
	5					
Other Membership Categories (Describe)	1					
	2					
	3					

Part 4: Appendices

II. Suggested Formats - Tables for New Applications: NCORP Research Bases List of Tables with Suggested Formats

	4					
	5					

Table 7. Summary of Onsite Auditing Activity for Cancer Prevention, Control and Screening Clinical Trials Over 5-Year Period (2008 – 2013)

THIS IS A SUMMARY TABLE ONLY. DO NOT INCLUDE SITE SPECIFIC INFORMATION. NCORP Research Base applicants should complete the table below to summarize their auditing activities over the 5-year period from 2008 - 2013. The table below should be modified to reflect membership categories of the NCORP Research Base applicant who have conducted DCP-funded cancer prevention, control and screening clinical trials. Sites that are terminated or withdrawn within the 5-year period & later re-activated should still be counted in these columns.

Participating Site Member Category	# Active Participating Sites with Separate NCI Institutional Codes as of Date Table Prepared	# Participating Sites WITHDRAWN Over 5-Year Period (2008 – 2013)	# Participating Sites WITHDRAWN Over 5-Year Period (2008 – 2013)	# Routine Audits Performed & % Routine Audits with Specific Ratings by Audit Category Over 5-Year Period (2008 – 2013)					# Re-Audits & Off Cycle Audits Performed and % Re-Audits & Off-Cycle Audits with Specific Ratings by Audit Category Over 5-Year Period (2008 – 2013)				
				Audit Category	# Routine Audits	% Acceptable	% Acceptable with Follow-Up	% Acceptable	Audit Category	# Routine Audits	% Acceptable	% Acceptable with Follow-Up	% Acceptable
Main Members				IRB/ICC					IRB/ICC				
				Pharm					Pharm				

Part 4: Appendices

II. Suggested Formats - Tables for New Applications: *NCORP Research Bases List of Tables with Suggested Formats*

				acy					acy				
				Pati ent Cas es					Pati ent Cas es				
Affilia tes of Main Mem bers				IRB /IC C					IRB /IC C				
				Pha rm acy					Pha rm acy				
				Pati ent Cas es					Pati ent Cas es				
CCOP s & MBC COPs				IRB /IC C					IRB /IC C				
				Pha rm acy					Pha rm acy				
				Pati ent Cas es					Pati ent Cas es				
CCOP & MBC COP Com pone nts				IRB /IC C					IRB /IC C				
				Pha rm acy					Pha rm acy				
				Pati ent Cas es					Pati ent Cas es				

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II. Suggested Formats - Tables for New Applications: *B. NCORP Community Site List of Tables with Suggested Formats*

Other Membership Categories (Describe)				IRB /IC C					IRB /IC C				
				Pharmacy					Pharmacy				
				Patient Cases					Patient Cases				

Table 8. Description of Biospecimens Collected in Conjunction with Cancer Prevention, Control and Screening Clinical Trials from 6/1/08 – 5/31/13

1) Trial Category	Trial Number & Brief Title	Biospecimen Laboratory Name/Location	# and Type Samples Collected	Date Samples Provided	Specimens Banked Y/N	Specimens Accessed by Qualified Researchers Y/N	Publication(s) Reference
Prevention							
Control							
Screening							

B. NCORP Community Site List of Tables with Suggested Formats

Table 1. NCORP Community Site Components and Sub-Components

Definition of Component: A hospital, cancer center, physician practice, or other institution where patients/participants are enrolled on a regular and ongoing basis to the menu of NCI-approved clinical trials available to the NCORP Community Site. In addition, one or more of the NCORP Site components are expected to participate in

Part 4: Appendices

II. Suggested Formats - Tables for New Applications: *B. NCORP Community Site List of Tables with Suggested Formats*

cancer care delivery research. Community Site awardee will be regarded as a "primary component".

A letter of agreement between the NCORP Community Site and each component(s) must be included in the grant application. OHRP assurance requirements must be met.

Definition of Sub-Component: A sub-component is a practice or organization that contributes to the overall accrual of a component site but is located in a separate geographic location(s), is part of the component's business entity and is managed by the primary component.

- 1) List each component followed by each component's sub-component(s) (if applicable) prior to listing the next component.
- 2) Indicate if component/sub-component is an integrated system, hospital, group/office practice, or other organization (indicate type).
 - a. If integrated system, indicate all applicable codes: 1 = Not for Profit, 2 = For Profit
 - b. If hospital, indicate all applicable codes: 1=Not for Profit; 2=Federal Government (VA or MTF); 3=For Profit; 4=State/County/City Government; 5=Teaching; 6=Medical School; 7=Approved Residency; 8=Formal Medical Affiliation with Student Rotation.
 - c. If group, indicate all applicable codes: 1=Not for profit; 2= For profit; 3=Larger practice corporation; 4=Hospital system; 5=Partnered with HMO; 6=Partnered with public hospital
- 3) If hospital, indicate if it has a current American College of Surgeons (ACOS) accredited cancer program.
- 4) If group, indicate if it has American Society of Clinical Oncology (ASCO) Quality Oncology Practice Initiative (QOPI) Certification or other similar certification program
- 5) Report new cases diagnosed or receiving primary treatment at that hospital or physicians group practice except for basal cell or squamous cell carcinoma of the skin.
- 6) Indicate average annual accrual over previous 5 calendar years for treatment, cancer prevention, control & screening trials.

1) Name of Component / Sub-Component Address Telephone	2) Description		Name of IRB Covering IRB Assurance #	FWA Number	NCICTEP Site Code	3) ACS CoC Accredited Program Y/N (Hospital s)	4) ASCO QOPI or Other Program Y/N	Total Number of Hospital Beds (Hospital s) 2012	5) Number of New Cancer Patients		6) Average 5-Year Annual Accrual	
	IS = Integrated	If Integrated							2011	2012	Treatment	Cancer Prevention

Part 4: Appendices

II. Suggested Formats - Tables for New Applications: B. NCORP Community Site List of Tables with Suggested Formats

Number	System H=Hospital G=Group S=Solo O=Other	System, Hospital or Group, enter applicable code (s)					(Group)					n, Control & Screening
Component #1												
Sub-Component #1												
Sub-Component #2												
Component #2												
Sub-Component #1												
Sub-Component #2												

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II. Suggested Formats - Tables for New Applications: B. NCORP Community Site List of Tables with Suggested Formats

Table 2a. NCORP Community Site Accrual Record – Treatment Clinical Trials

CCOP Research Base	Number of Accruals				
	6/08 – 5/09	6/09 – 5/10	6/10 – 5/11	6/11 – 5/12	6/12 – 5/13
Example: SWOG	63	75	55	70	40
Total					

Table 2b. NCORP Community Site Accrual Record – Cancer Prevention, Control & Screening Clinical Trials

CCOP Research Base	Number of Accruals				
	6/08 – 5/09	6/09 – 5/10	6/10 – 5/11	6/11 – 5/12	6/12 – 5/13
Example: SWOG	63	75	55	70	40
Total					

Table 3a. NCORP Community Site Currently Active Clinical Trials

1. List clinical trials by category (i.e., Treatment, followed by Prevention followed by Control followed by Screening) and CCOP Research Base

1) Trial Category	Research Base	Trial Number & Brief Title	Date Open for Patient Accrual	Accrual to Date
Treatment				
Prevention				

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II. Suggested Formats - Tables for New Applications: B. NCORP Community Site List of Tables with Suggested Formats

Control				
Screening				

Table 3b. NCORP Community Site NCI Clinical Trials Expected to Activate over the next 12 months

List clinical trials by category (i.e., Treatment, followed by Prevention followed by Control followed by Screening) and CCOP Research Base

1) Trial Category	Research Base	Trial Number & Brief Title	Comment
Treatment			
Prevention			
Control			
Screening			

Table 4. Current and/or Planned Research Base Affiliation(s)

Name of Research Base	Treatment Research Y/N	Cancer Prevention, Control and Screening Research Y/N	Cancer Care Delivery Research Y/N

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II. Suggested Formats - Tables for New Applications: B. NCORP Community Site List of Tables with Suggested Formats

Table 5. NCORP Community Site Cancer Care Delivery Research Study (CCDR) Capabilities

Provide this information for only the component(s) which are participating in CCDR

- 1) Indicate average annual accrual over previous 5 calendar years to CCDR studies
- 2) Indicate patient insurance coverage type and percentage: 1=Group, 2=Individual, 3=Medicaid, 4=Medicare, 5=Other public
- 3) 1 = On-site genetic counseling, 2 = On-site genetic testing
- 4) 1 = Hospice team at facility, 2 = Contracted hospice services, 3 = Outpatient hospice beds
- 5) 1 = Screening, 2 = Treatment, 3 = Survivorship
- 6) 1 = On-site pharmacy, 2 = Clinical trials pharmacy, 3 = Patient education

	Component Name	Component Name	Component Name	Component Name
1) Average 5-year Annual Accrual				
2) Insurance Coverage				
Specialty Services				
Behavioral Health				
Cardiology				
Dental care/Oral Medicine				
Emergency Room Facility				
Endocrinology				
3) Genetic Counseling				
4) Hospice Program				
Hospitalist				
Nutrition/Dietetics				
Pain Management Program				
Pediatrics				

Part 4: Appendices

II. Suggested Formats - Tables for New Applications: B. NCORP Community Site List of Tables with Suggested Formats

Physical/Occupational/Rehabilitation Therapy				
Radiology				
Surgery				
5) Navigation				
6) Pharmacy				
Social Work				
Palliative care Program				
Quality improvement program				
Genetics, genomics, bio-repositories				
Tobacco control/smoking cessation				

Table 6. NCORP Community Site Cancer Care Delivery Research Study Accrual Record –

CCOP Research Base	Number of Accruals				
	6/08 – 5/09	6/09 – 5/10	6/10 – 5/11	6/11 – 5/12	6/12 – 5/13
Example: SWOG	63	75	55	70	40
Total					

Table 7. Summary of CCOP Research Base Auditing for Treatment, Cancer Prevention, Control and Screening Clinical Trials over Previous 5 Years (June 1, 2008 – May 31, 2013)

1. Type of Audit = Routine, Re-audit or For Cause Audit

2. Indicate rating by "✓" or "X" in applicable rating per category

CCOP Research Base Name	Date (s) of	1) Type of	# of Patient	2) Audit Rating by Audit Category				
				Audit	Accep	Accep	Unacce	Re-audit

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II. Suggested Formats - Tables for New Applications: *B. NCORP Community Site List of Tables with Suggested Formats*

	Audit	Audit	Cases Reviewed	Category	table	table with Follow-Up	ptable	Required ? Y/N
				IRB/IC C				
				Pharmacy				
				Patient Cases				
				IRB/IC C				
				Pharmacy				
				Patient Cases				
				IRB/IC C				
				Pharmacy				
				Patient Cases				
				IRB/IC C				
				Pharmacy				
				Patient Cases				
				IRB/IC C				
				Pharmacy				

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II. Suggested Formats - Tables for New Applications: B. NCORP Community Site List of Tables with Suggested Formats

				Patient Cases				
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Table 8. Number of Newly Diagnosed Cancer Patients by Site

Directions: Provide figures for the table below to the extent possible. Use new cases diagnosed or receiving treatment at that hospital, except for basal cell or squamous cell carcinoma of the skin. Submit a separate sheet for each hospital component.

Name of Component/Sub-Component(s): _____

Information Source: **Hospital Registry** **Regional Registry**
 Population Based Registry
 Hospital Discharge Data **Other**

	Calendar Year			Calendar Year	
	2011	2012		2011	2012
Breast Tumor			Non-Small Cell Lung		
Esophagus			Hodgkin's Disease		
Stomach			Non-Hodgkin's Disease		
Pancreas			Kaposi's Sarcoma		
Hepatobiliary			Melanoma		
Colon			Head/Neck Tumors		
Rectum			Brain/Other CNS Tumors		
GI (other)			Endocrine		
Bladder			Osteogenic Sarcoma		
Kidney			Soft Tissue Sarcoma		
Prostate			Rhabdomyosarcoma		
Testis			Ewing's Sarcoma		
GU (other)			Sarcoma (other)		

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II. Suggested Formats - Tables for New Applications: B. NCORP Community Site List of Tables with Suggested Formats

	Calendar Year			Calendar Year	
	2011	2012		2011	2012
Cervix			Wilm's Tumor		
Ovary			Neuroblastoma		
Uterus, Endometrial			Pediatric ALL		
GYN (other)			Pediatric AML		
Myeloma			Pediatric Acute Leukemia (other)		
Adult Acute Lymphocytic			Pediatric Lymphomas incl.		
Adult Acute Non- Lymphocytic			Pediatric Solid Tumors/Others		
Chronic Leukemia			Other		
Small Cell Lung			TOTAL:		

Part 4: Appendices

Guidelines and Sample Calculations for Total Cost Budget Estimations for NCORP Research Bases, Community Sites and Minority/Underserved Sites: *Guidelines for Estimating Research Base Total Cost Budget Requests – Type 1 Application*

II. Guidelines and Sample Calculations for Total Cost Budget Estimations for NCORP Research Bases, Community Sites and Minority/Underserved Sites

NOTE: Applicants are not required to use the sample calculation worksheets B., C., or D. below in estimating their budgets. These worksheets are offered as a sample, only. Applicants should propose a budget that includes the appropriate costs and amounts that reflect the scope of the research proposed.

A. Guidelines for Estimating Research Base Total Cost Budget Requests – Type 1 Application

TOTAL COST Unit_Value for Type 1 Applications: \$500

Study Categories for Estimating Research Base "Per Case Management" Funding for Institutional Members	Unit Multiplier	Total Cost Value (Total Cost Unit Value of \$500 x Credit Multiplier)	"Per Case Management" Funding Category
Basic Intervention (Prevention, Cancer Control and/or Screening/Post-Treatment Surveillance Studies)	4.5	\$2250	Intervention
Pilot Intervention (Prevention, Cancer Control and/or Screening/Post-Treatment Surveillance Studies)	4.5	\$2250	Intervention
Health Related Quality of Life	2	\$1000	HRQOL
Molecular Screening (subjects who receive only molecular screening)	1	\$500	Supplementary
Biospecimen Collection	1	\$500	Supplementary
Total Cost for Financial Management of "Per Case Management" Funding % of Total Cost of "Per Case Management" Funding for Different "Per Case Management" Funding Categories (Suggested Range for %)	Intervention Category	Health Related Quality of Life Category	Supplementary Category
	10% to 20%	5% to 10%	5% to 10%
Total Cost for Research Base Infrastructure Based on \$ Multiplier for Accrual to NCORP Trials led by the Research Base for Different "Per Case Management" Funding Categories (Suggested Range for \$ Multiplier)	Intervention Accrual (Per Enrolled Patient)	Health Related Quality of Life Accrual (Per Enrolled Patient)	Supplementary Accrual (Per Enrolled Patient)
	\$1800 to \$2000	\$900 to \$1100	\$300 to \$500

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Guidelines and Sample Calculations for Total Cost Budget Estimations for NCORP Research Bases,
Community Sites and Minority/Underserved Sites: **Estimating Type 1 Application Research Base**
Total Cost Budget Request - Sample Calculation

B. Estimating Type 1 Application Research Base Total Cost Budget Request - Sample Calculation

Total Cost Unit Value for Type 1 Application	\$500	\$500	\$500	\$500	\$500
TOTAL COST FOR "Per Case Management" Funding for Research Base Institutional Members by Funding Category	Basic Intervention (Prevention, Cancer Control, Screening/Post-Treatment Surveillance)	Pilot Intervention (Prevention, Cancer Control Screening/Post-Treatment Surveillance)	Health Related Quality of Life	Molecular Screening Only	BiospecimenCollection
Unit Multiplier for Category	4.5	4.5	2	1	1
Value of "Per Case Mgt" Funding Category (Unit Value x Unit Multiplier)	\$2,250	\$2,250	\$1,000	\$500	\$500
# of Patients Projected to be Enrolled to NCORP Trials Led by Applicant Research Base by Applicant’s Institutional Members and Credited to Applicant Research Base	600	35	650	70	75
Total Cost "Per Case Mgt" Funding (Trials led by Applicant Research Base) (# Patients x Value of "Per Case Mgt" Funding)	\$1,350,000	\$78,750	\$650,000	\$35,000	\$37,500
# of Patients Projected to be Enrolled to NCORP Trials Led by Another Research Base by Applicant’s Institutional Members and Credited to Applicant Research Base	70	15	40	20	15
Total Cost "Per Case Mgt" Funding (Trials led by Another Research Base) (# Patients x Value of "Per Case Mgt" Funding)	\$157,500	\$33,750	\$40,000	\$10,000	\$7,500
Total Cost "Per Case Mgt" Funding for Enrollment Credited to Applicant Research Base by Category	\$1,507,500	\$112,500	\$690,000	\$45,000	\$45,000
Total Cost "Per Case Mgt" Funding for Enrollment Credited to Applicant Research Base - All Categories	\$2,400,000				
Total Cost Financial Management of "Per Case Mgt" Funding for All Categories at 10%	\$240,000				
Total Cost "Per Case Mgt" Funding & Financial Mgt	\$2,640,000				
TOTAL COST BUDGET FOR RESEARCH BASE INFRASTRUCTURE					
# Pts Enrolled Annually on NCORP Trials Led by Research Base - Basic Intervention		1200			
# Pts Enrolled Annually on NCORP Trials Led by Research Base – Pilot Intervention		70			
#Pts Enrolled Annually on NCORP Trials Led by Research Base - All Intervention		1270			
# Pts Enrolled Annually on NCORP Trials Led by Research Base - Health Related Quality of Life		800			
# Pts Enrolled Annually on NCORP Trials Led by Research Base- Molecular Screening Only		150			
# Pts Enrolled Annually on NCORP Trials Led by Research Base – Biospecimen Collection		150			
# Pts Enrolled Annually on NCORP Trials Led by Research Base - All Supplementary		300			

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Guidelines and Sample Calculations for Total Cost Budget Estimations for NCORP Research Bases, Community Sites and Minority/Underserved Sites: ***Estimating Total Cost Budget Request for*** Basic Level NCORP Community & Minority/Underserved Community Sites – Sample Calculation

	Low Range Per Patient	High Range Per Patient
Total Cost for Infrastructure – Intervention Studies (\$1800 to \$2200 per patient)	\$2,286,000	\$2,794,000
Total Cost for Infrastructure - HRQOL Studies (\$900 to \$1100 per patient)	\$720,000	\$880,000
Total Cost for Infrastructure – Supplementary Studies (\$300-500 per patient)	\$90,000	\$150,000
Total Cost for Infrastructure – All Studies	\$3,096,000	\$3,824,000
Total Cost for Research Base Application	\$5,736,000	\$6,464,000

C. Estimating Total Cost Budget Request for High Performance* NCORP Community & Minority/Underserved Community Sites – Sample Calculation

Credit Category (see Note below)	Multiplier	Average # of Credits/Year (based on prior 3 years)	Category Totals
Treatment Trial Credits	\$4,000	175	\$700,000
Advance Imaging Credits	\$4,000	30	\$120,000
Health Related Quality of Life Credits	\$4,000	75	\$300,000
Prevention, Control and/or Screening/Post Treatment Surveillance Trials Credits	\$4,000	300	\$1,200,000
Molecular Screening Credits	\$4,000	5	\$20,000
Biospecimen Collection Credits**	\$4,000	5	\$20,000
Infrastructure funding	\$250,000 - \$300,000	NA	\$275,000
Grand Total Cost Budget Request for Application			\$2,635,000

Note: Treatment, prevention, control and screening/post treatment surveillance trials generally received 1 credit per accrual; health-related quality of life and advanced imaging studies generally receive 0.5 credits per accrual and molecular screening and biospecimen collection generally receive 0.1 credits per accrual.

**** Note: Do not report credits for biospecimen collections paid for by non-NCI funding sources (i.e., industry funding, foundations, etc.)**

D. Estimating Total Cost Budget Request for Basic Level NCORP Community & Minority/Underserved Community Sites – Sample Calculation

Credit Category (see Note below)	Multiplier	Average # of Credits/Year	Category Totals
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Guidelines and Sample Calculations for Total Cost Budget Estimations for NCORP Research Bases, Community Sites and Minority/Underserved Sites: ***Estimating Total Cost Budget Request for*** Basic Level NCORP Community & Minority/Underserved Community Sites – Sample Calculation

(based on prior 3 years)			
Treatment Trial Credits	\$2,500	75	\$187,500
Advanced Imaging Credits	\$2500	10	\$25,000
Health Related Quality of Life Credits	\$2,500	45	\$112,500
Prevention, Control and/or Screening/Post Treatment Surveillance Trials Credits	\$2,500	100	\$250,000
Molecular Screening Credits	\$2,500	5	\$12,500
Biospecimen Collection Credits**	\$2,500	5	\$12,500
Infrastructure funding	\$250,000 - \$300,000	NA	\$265,000
Grand Total Cost Budget Request for Application			\$865,000

Note: Treatment, prevention, control and screening/post treatment surveillance trials generally received 1 credit per accrual; health-related quality of life and advanced imaging studies generally receive 0.5 credits per accrual and molecular screening and biospecimen collection each receive 0.1 credits per accrual.

**** Note: Do not report credits for biospecimen collections paid for by non-NCI funding sources (i.e., industry funding, foundations, etc.)**

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Other Important NCI/NIH URLs, Federal Citations, and List of Abbreviations: *Website URLs referenced in these Guidelines*

III. Other Important NCI/NIH URLs, Federal Citations, and List of Abbreviations

A listing of important URLs (links to websites) and abbreviations referenced in the text of these Guidelines is provided below.

A. Website URLs referenced in these Guidelines

NCI Website

<http://www.cancer.gov/>

NCI Biomarker, Imaging, and Quality of Life Studies Funding Program (BIQSFP)

<http://biqsfp.cancer.gov/>

NCI Cancer Trials Support Unit (CTSU) Website

<http://www.ctsu.org>

NCI Cancer Diagnosis Program's Request for an Application (RFA) on Support for Human Specimen Banking in NCI-Supported Cancer Clinical Trials

<http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-05-017.html>

NCI Cancer Diagnosis Program's Website

<http://cdp.cancer.gov/>

NCI Center for Coordinating Clinical Trials

<http://ccct.cancer.gov/about/overview>

NCI Central IRB Website

<http://www.ncicirb.org>

NCI Clinical Trials and Translational Research Advisory Committee (CTAC)

<http://ccct.cancer.gov/committees/ctac>

NCI Clinical and Translational Research Operations Committee

<http://ccct.cancer.gov/committees/ctroc>

NCI CTWG Steering Committee System (Information on NCI Scientific Steering Committees)

<http://transformingtrials.cancer.gov/steering/overview>

NCI Clinical Trials Reporting Program (CTRP)

<http://www.cancer.gov/clinicaltrials/conducting/ncictrp/main/allpages>

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Other Important NCI/NIH URLs, Federal Citations, and List of Abbreviations: *Website URLs referenced in these Guidelines*

NCI Guide to Readers to Information on Other NCI Divisions/Branches

<http://www.cancer.gov/aboutnci>

Diagnostics Evaluation Branch (DRB) of the Cancer Diagnosis Program (CDP) Program for the Assessment of Clinical Cancer Tests (PACCT) – Clinical Tumor Marker Study Guidelines
<http://www.cancerdiagnosis.nci.nih.gov/diagnostics/advice/guidelines.htm>

Good Clinical Practice in FDA-Regulated Clinical Trials

<http://www.fda.gov/oc/gcp/default.htm>

Guidance Document on Inclusion of Manuscripts/Publications in Appendix Material with NIH/NCI Grant Applications

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-053.html>

NIH Data Sharing Policy

http://grants.nih.gov/grants/policy/data_sharing

NIH Freedom of Information Act Office

<http://www.nih.gov/icd/od/foia/index.htm>

NIH Grants Policy Statement

<http://grants.nih.gov/grants/policy/policy.htm>

NIH Grant Policy for Program Income

http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch8.htm#_Program_Income

NIH Guide Notice on NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (Amendment October 2001).

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>

NIH Public Access Policy (and Manuscript Submission System)

<http://publicaccess.nih.gov>

NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects (3/6/98)

<http://www.nih.gov/grants/guide/notice-files/not98-024.html>

NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended, October, 2001 (COMPLETE COPY OF UPDATED GUIDELINES)

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

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Other Important NCI/NIH URLs, Federal Citations, and List of Abbreviations: *Other Federal Citations for NIH Grants* Involved in Human Subjects Research & Websites

NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects – Policy Implementation

<http://grants.nih.gov/grants/funding/children/children.htm>

NIH Policy for Data and Safety Monitoring

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>

(Further) NIH Guidance on Data and Safety Monitoring for Phase 1 and Phase 2 trials

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>

NIH Policies on Inclusion of Women and Minorities as Participants in Research Involving Human Subjects – Policy Implementation

http://grants.nih.gov/grants/funding/women_min/women_min.htm

NIH Policy on Financial Conflict of Interest

<http://grants.nih.gov/grants/policy/coi>

PHS 398 Grant Application

<http://grants.nih.gov/grants/funding/phs398/phs398.html>

PHS 2590 Non-Competing Grant Progress Report

<http://grants.nih.gov/grants/funding/2590/2590.htm>

SF424 (R&R) Application and Electronic Submission Information

<http://grants.nih.gov/grants/funding/424/index.htm>

Office for Human Research Protections Website

<http://www.hhs.gov/ohrp/>

Required Education on the Protection of Human Subject Participants

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>

Updated Instructions Regarding Inclusion of Publications as Appendix Materials:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-077.html>

B. Other Federal Citations for NIH Grants Involved in Human Subjects Research & Websites

Sharing of Model Organisms

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see

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Other Important NCI/NIH URLs, Federal Citations, and List of Abbreviations: *Other Federal Citations for NIH Grants* Involved in Human Subjects Research & Websites

http://grants.nih.gov/grants/policy/model_organism/index.htm).

At the same time, the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh-Dole Act (see the NIH Grants Policy Statement at

http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch8.htm#_Program_Income).

All investigators submitting an NIH application or contract proposal, beginning with the October 1, 2004, receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Standards for Privacy of Individually Identifiable Health Information

This Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR). Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

Healthy People 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. The funding opportunity announcement (FOA) for this cooperative agreement is related to one or more of the priority areas. Potential applicants can obtain a copy of "Healthy People 2010" at

<http://www.health.gov/healthypeople>.

Authority and Regulations

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Other Important NCI/NIH URLs, Federal Citations, and List of Abbreviations: *Other Federal Citations for NIH Grants* Involved in Human Subjects Research & Websites

This program is described in the Catalogue of Federal Domestic Assistance at <https://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service (PHS) Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American People.

Loan Repayment Program

NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The Loan Repayment Program (LRP) is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40-hour week) for 2 years to the research. For further information, please see <http://www.lrp.nih.gov/>.

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Other Important NCI/NIH URLs, Federal Citations, and List of Abbreviations: *Important Abbreviations Referenced in these Guidelines*

C. Important Abbreviations Referenced in these Guidelines

ABBREVIATION	FULL TERM
AD	Associate Director, CTEP, DCTD
AdEERS	Adverse Event Expedited Reporting System
ARA	Awaiting Receipt of Application
BIQSFP	Biomarker, Imaging, and Quality of Life Studies Funding Program
BRB	Biometric Research Branch (in DCTD)
CBO	Common Budget Outline
CCCT	Coordinating Center for Clinical Trials (in NCI OD)
CCOP	Community Clinical Oncology Program (in DCP)
CDE	Common Data Elements
CDP	Cancer Diagnosis Program (in DCTD)
CDUS	Clinical Data Update System
CFR	Code of Federal Regulations
CIB	Clinical Investigations Branch (in CTEP)
CIP	Cancer Imaging Program (in DCTD)
CIRB	Central Institutional Review Board at NCI
CRA	Clinical Research Associate
CRADA	Cooperative Research and Development Agreement
CSA	Clinical Supply Agreement
CSR	Center for Scientific Research (at NIH)
CTA	Clinical Trial Agreement
CTAC	Clinical Trials and Translational Research Advisory Committee

Part 4: Appendices

Other Important NCI/NIH URLs, Federal Citations, and List of Abbreviations: *Important Abbreviations Referenced in these Guidelines*

CTCAE	Common Toxicity Criteria for Adverse Events
CTEP	Cancer Therapy Evaluation Program (in DCTD)
CTMB	Clinical Trials Monitoring Branch (in CTEP)
CTSU	Cancer Trials Support Unit
CTRP	Clinical Trials Reporting Program
CTWG	Clinical Trials Working Group
CTROC	Clinical and Translational Research Operations Committee
DAR	Drug Accountability Record
DCP	Division of Cancer Prevention
DCTD	Division of Cancer Treatment and Diagnosis
DEA	Division of Extramural Activities
DHHS	Department of Health and Human Services
DMC	Data Monitoring Committee (also known as Data and Safety Monitoring Board)
DRB	Diagnostics Evaluation Branch (in CDP)
DSMB	Data and Safety Monitoring Board (also known as Data Monitoring Committee)
FDA	Food and Drug Administration
FWA	Federal wide Assurance (for OHRP)
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IDB	Investigational Drug Branch (in CTEP)
IND	Investigational New Drug Application
IRB	Institutional Review Board
LOI	Letter of Intent
NCAB	National Cancer Advisory Board
NCI	National Cancer Institute

Part 4: Appendices

Other Important NCI/NIH URLs, Federal Citations, and List of Abbreviations: *Important Abbreviations Referenced in these Guidelines*

NCI SSC	NCI Scientific Steering Committees
NIH	National Institutes of Health
NCTN	National Clinical Trials Network
OD	Office of the Director at the NCI
OEWG	Operational Efficiency Working Group
OGA	Office of Grants Administration
OHRP	Office for Human Research Protections
OPEN	Oncology Patient Enrollment Network
ORI	Office of Research Integrity
PD	Program Director
PHS	Public Health Service
PI	Principal Investigator
PIO	Protocol and Information Office (in CTEP)
PMB	Pharmaceutical Management Branch (in CTEP)
PRC	Protocol Review Committee (in CTEP – also known as NCI/DCTD PRC)
RAB	Regulatory Affairs Branch (in CTEP)
RRP	Radiation Research Program (in DCTD)
RSS	Regulatory Support System (in CTSU)
SDMC	Statistics and Data Management Center
SOP	Standard Operating Procedure
SPORE	Specialized Programs of Research Excellence
SRO	Scientific Review Officer
URL	Uniform Resource Locator (internet address of resource)

IV. Sample Table of Contents for PHS 398 Application (Example NCORP Research Base): *Important Abbreviations Referenced in these Guidelines*

**IV. Sample Table of Contents for PHS 398 Application
(Example NCORP Research Base)**

SECTION I

Face Page

**Description, Project/Performance Sites, Senior/Key Personnel, Other
Significant Contributors,
& Human Embryonic Stem Cells**

Research Grant Table of Contents

**Detailed Budget for Initial Budget Period & Budget for Entire Proposed Period
of Support**

- **Plus Common Budget Outline**
- **Accrual Input by Member Institution/Sites Used to Generate Part of
Network Group Ops Center Budget**

Budget Pertaining to Consortium/Contractual Arrangements

Biographical Sketch

Program Director(s)/Principal Investigator(s) (*Not to exceed four pages each*)

- **Other Biographical Sketches (*Not to exceed four pages each – See
instructions*)**
- **Other Support Information**

Resources

- **Include Required Tables**
- **Include Key SOPs**

SECTION II

Research Plan

Specific Aims (including Impact Statement)

Research Strategy Sections

- A. Research Base Overview and Leadership (up to 12 pages)**
- B. Cancer Prevention, Control, Screening Clinical Trial Development
Program (up to 12 pages)**
- C. Statistical Analysis/Data Management for Cancer Prevention,
Control and Screening Clinical Trials (up to 12 pages)**
- D. Cancer Care Delivery Research Program (up to 12 pages)**
- E. Operational Management (up to 12 pages)**
- F. Collaboration and NCORP Collective Management (up to 12
pages)**

Bibliography and References Cited

Protection of Human Subjects

Inclusion of Woman and Minorities

Targeted/Planned Enrollment Table

Inclusion of Children

Vertebrate Animals

Select Agent Research

Part 4: Appendices

IV. Sample Table of Contents for PHS 398 Application (Example NCORP Research Base): *Important Abbreviations Referenced in these Guidelines*

Multiple Program Director/Principal Investigator (PD(S)/PI(S))
Leadership Plan
Consortium/Contractual Arrangements
Letters of Support (e.g., Consultants)
Resource Sharing Plans

Checklist
Appendix

Part 4: Appendices

V. Model for NCORP Program Data Sharing Policy for Research Base Ops Centers & SDMCs:

Introduction

V. Model for NCORP Program Data Sharing Policy for Research Base Ops Centers & SDMCs

Introduction Guidelines for Availability of Datasets Request Procedure Regulatory Considerations Release Conditions & Disclaimer Appeals Process Fees
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A. Introduction

This document describes general policies of the NCI Community Oncology Research (NCORP) Program for funded Research Bases (which for a NCORP Research Base application that also is a funded NCTN Group is the combination of a NCTN Operations Center and its associated NCTN Statistical and Data Management Center) on providing individual patient data to investigators for use in research projects. Each Research Base may have a more detailed set of procedures implementing the general policy but those procedures should be consistent with all provisions of the general policy.

The Research Bases conduct clinical trials in cancer prevention, control, screening and studies in cancer care delivery. Each NCORP Research Base or NCORP study has a formal protocol document, which includes a statement of the objectives of the study. Patient consent and authorization are obtained to collect the individual patient data required for addressing the study objectives. These data are sent from the treating or enrolling institution to the Research Base's Statistics and Data Management Center, where the data are reviewed, processed and entered on an electronic database. The data may be submitted on paper or electronically. Not all information submitted on paper becomes part of the electronic database. The electronic database is used as the basis for the analysis of the Research Base's studies, with the analyses performed by the staff at the Research Base's Statistics and Data Management Center.

The procedures described here do not cover requests from the NCI, FDA or other federal agencies for information required by federal regulations or by the terms of the Research Bases' grant awards. Such requests will be honored as expeditiously as possible.

This document only covers requests for existing data, not requests for use of biospecimens (which are covered under a different evaluation and review process) or for collection of additional data. Requests for individual-level genomic or other high-dimensional data not used in the primary publication may be subject to other NCI and NIH regulations.

Part 4: Appendices

V. Model for NCORP Program Data Sharing Policy for Research Base Ops Centers & SDMCs: *Request* Procedure

The data requested by an investigator may include data generated from laboratory correlative studies. However, this document only covers requests for existing data, not requests for use of tissue or for collection of additional data.

B. Guidelines for Availability of Datasets

For phase 3 studies, it is anticipated that individual-level de-identified datasets that would be sufficient to reproduce results provided in a publication (i.e., published manuscript) containing the primary study analysis would be available to individuals via the requesting procedure described in Section 3 generally within 6 months of publication of the manuscript. It is anticipated that datasets containing patient-level entry data of all baseline variables summarized in the publication would be available within 12 to 15 months after the publication of the primary analysis.

For non-phase 3 studies, a patient dataset containing the variables analyzed in the primary results paper would be expected to be available upon request (subject to restrictions stated in Section 4). This process could take several months. Since these studies could be quite small, the release of data may be constrained by the ability to de-identify data.

For publications that are not presenting the primary analysis of the trial, patient datasets containing the variables analyzed in the paper should be available upon request (subject to restrictions stated in Section 4). This process could take several months.

Release of data collected in a clinical trial conducted under a binding collaborative agreement between the NCI Division of Cancer Prevention and a pharmaceutical/biotechnology company must be in compliance with the terms of the binding collaborative agreement and must be approved by DCP and the company. Release of the data is also subject to the terms of any contracts between the Research Base and other entities, which cover any of the requested data. These two considerations could, in some instances, delay the release of data to requesting investigators.

C. Request Procedure

While most analyses of the Research Base's studies are performed at the Research Base Statistics and Data Management Center, the Research Base also makes research data available to other investigators, as required by the policies of the National Institutes of Health. An investigator who wishes to use individual patient data from one or more of the Research Base's studies must make a formal request to the Research Base Operations Center.

The Research Base Operations Center will typically require documentation of Institutional Review Board (IRB) approval (or exemption) from the institution of the requesting investigator which should include a brief description of the project; see Section 4 below. The Research Base

Part 4: Appendices

V. Model for NCORP Program Data Sharing Policy for Research Base Ops Centers & SDMCs: *Regulatory* Considerations

Operations Center may also require IRB approval or exemption from the IRB associated with the Research Base Statistics and Data Management Center. The Research Base Operations Center will also typically require the investigator to sign a data use agreement specifying who will have access to the individual patient data and specifying that it will not be shared with others outside this specified set of individuals.

The Research Base website should contain a list of the available collections of datasets from their clinical trials, the request procedure, and who to contact to obtain these collections.

There should be no scientific review of requests for data. If a Research Base is unable to fulfill a request, the Research Base must inform the investigators of the reasons the request cannot be fulfilled. In most cases it is likely the investigators will be able to amend the request to comply with the procedures. If the Research Base believes the request will not be amendable, the Research Base will inform the investigator of the appeal process outlined in Section 6 and also notify the Chief, Community Oncology and Prevention Trials Research Group (COPTRG), in the Division of Cancer Prevention (DCP) at the NCI who is also the Lead NCORP Program Director. Release of the data is subject to the disclaimer in Section 5.

D. Regulatory Considerations

All research use of data collected on human subjects from NCORP studies led by the Research Base is subject to applicable Office of Human Research Protections (OHRP) regulations and to applicable regulations of the Privacy Rule of the Health Insurance Portability and Accountability Act. Generally, patients have only consented to have their health information used for the objectives of the clinical trial in which they participated. Use of the data for other research projects is allowed only if an IRB has determined that use of the data in the project meets the minimal risk criteria for conducting the research without the patients' consent, if the use of the data in the project is exempt from consent requirements, or if the project does not constitute human subjects research. The required level of review or approval will generally depend on the degree to which the data have been rendered fully anonymous, de-identified, or coded.

Guidance on these matters can be found in the OHRP document "Guidance on Research Involving Coded Private Information or Biological Specimens" (<http://www.hhs.gov/ohrp/policy/cdebiol.html>) and at the NIH HIPAA Privacy Rule Information for Researchers site (http://privacyruleandresearch.nih.gov/clin_research.asp). The criteria for de-identification of data under HIPAA are given in the Code of Federal Regulations, Part 46, Section 164.514. It should be possible to conduct most projects using coded data (as described in the OHRP Guidance) that meet the criteria for a limited data set that can be released under a data use agreement (as described in Part 46 of the CFR, Section 164.512 and in the NIH HIPAA guidance documents), without obtaining additional patient consent or authorization.

Part 4: Appendices

V. Model for NCORP Program Data Sharing Policy for Research Base Ops Centers & SDMCs:

***Appeals* Process**

(**NOTE:** Each Research Base may need to add extra requirements imposed by the IRB's covering their Centers.)

E. Release Conditions & Disclaimer

A simple, formal data use agreement specifying who will have access to the individual patient data (and specifying that it will not be shared with others outside this specified set of individuals) as well as covering the release conditions described below and the regulatory considerations described in Section 4 above will usually be required.

It is anticipated that most data requests can be provided as non-complex data sets in electronic form. If possible, data sets from Research Base trials may be provided to the public via a website to facilitate access in the future.

It will sometimes be the case that the data requested for analysis will not all be coded on the Research Base's database but will be available in the paper charts at in the Research Base's Statistics and Data Management Center. In this case, the data will need to be abstracted from the charts. Data abstractions can only be performed if adequate funding to support the abstraction is available. Even if funding is available, the Research Base may not have staff available to perform the abstraction. In this case, the Research Base may be willing to have the investigators or their representatives or contractors come to the Research Base Statistics and Data Management Center to perform the abstraction. Some funding for clerical support may still be required. Likewise, in cases in which data requested require data sets not available in easily obtained electronic format, especially older trials, the Research Base may require some funding for support to create the dataset in a simplified electronic format.

In releasing the data, the Research Base makes no representations and extends no warranties of any kind, either expressed or implied. There are no expressed or implied warranties of merchantability or fitness for a particular purpose, or that the use of the data will not infringe any patent, copyright, trademark, or other proprietary rights. No indemnification for any loss, claim, damage, or liability will be intended or provided.

Copies of any manuscript arising from the project associated with the data request should be sent to the Research Base Operations Center; however, approval of the manuscript is not a condition for use of the data.

F. Appeals Process

If a request for data is denied, the applicant may appeal the decision. The appeal will be reviewed by the designated, the Lead NCORP Program Director, DCP Deputy Director or his/her designee, and an outside statistician (i.e., a statistician that does not work for the Research Base). The outside statistician will be named jointly by the designated and the Lead NCORP Program Director.

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V. Model for NCORP Program Data Sharing Policy for Research Base Ops Centers & SDMCs: *Fees*

G. Fees

Routine costs associated with preparing standard data sets are viewed by NCI as covered by the grant for the Research Base funded under the NCORP Program and fees should not be charged for release of non-complex electronic data sets. For complex data sets where substantial work is involved, fees may be charged for preparing and documenting the data set. Any fees will be limited to the actual time, effort and materials required for preparing and documenting the data set.

Part 4: Appendices

VIII. NCORP Program Data and Safety Monitoring Board (DSMB) Policy for Phase 3 Trials & Randomized Phase 2 Trials (also known as the Data Monitoring Committee (DMC) Policy): *Membership*

VIII. NCORP Program Data and Safety Monitoring Board (DSMB) Policy for Phase 3 Trials & Randomized Phase 2 Trials (also known as the Data Monitoring Committee (DMC) Policy)

A. Studies to be Monitored

One or more Data and Safety Monitoring Boards (DSMBs) or Data Monitoring Committees (DMCs) will be established to monitor all phase 3 and randomized phase 2 cancer prevention, control and screening trials conducted by NCORP Research Bases. Whereas a single DSMB/DMC per NCORP Research Base within the NCORP, is acceptable and may provide the most feasible way of maximizing independence of the DSMB/DMC, separate DSMBs/DMCs could be approved by the NCORP Director and Co-Director. This could be for single large trials, especially those that involve substantial risk/benefit oversight, or for a group of trials if the volume of trials to be monitored requires an additional DSMB/DMC because of workload issues.

B. Responsibilities

- The primary responsibility of the DSMB/DMC is to review interim analyses of outcome data (prepared by the study statistician) and to recommend whether the study needs to be changed or terminated based on these analyses. For phase 3, phase 2/3, and blinded randomized phase 2 trials, the committee also determines whether and to whom outcome results should be released prior to the reporting of study results at the time specified in the protocol.
- The DSMB/DMC reviews reports of related studies performed by the Network Groups and NCORP Research Bases to determine, considering information and recommendations supplied by the study committee, whether the group study needs to be changed or terminated.
- The DSMB/DMC reviews interim toxicity data although that is primarily the responsibility of the study committee.
- The DSMB/DMC reviews major modifications to the study proposed by the study committee prior to their implementation (e.g., termination, dropping an arm based on toxicity results or other trials reported, increasing target sample size).

C. Membership

If the NCORP Research Base chooses to use the NCTN DSMC, please refer to the NCTN's Guidelines for membership requirements. A designee named by the Division of Cancer Prevention (DCP) Community Oncology and Preventive Trials Research Group (COPTRG) program director will be a non-voting member and must be free to attend all sessions.

Part 4: Appendices

VIII. NCORP Program Data and Safety Monitoring Board (DSMB) Policy for Phase 3 Trials & Randomized Phase 2 Trials (also known as the Data Monitoring Committee (DMC) Policy): *Meetings*

If the designated NCORP Research Base chooses to create a separate DSMC/DMC for its trials, they will be appointed for a fixed term by the designated NCORP Research Base Principal Investigator (PI) for the NCORP Research Base with the approval of the NCORP Director and Co-Director. The nominees should be reviewed and approved by NCI/DCP with written confirmation by the Director and Co-Director, NCORP prior to their official appointment and participation in DSMB/DMC activities. The committee will include physicians and statisticians from within and outside the NCORP Research Base selected based on their experience, reputation for objectivity, absence of conflicts of interest (or the appearance of same), and knowledge of good clinical trial methodology. The committee must include a consumer representative and a voting statistician from outside the group. A NCI/DCP Program Director and a NCI/DCP statistician, as designated by the NCORP Director and Co-Director will be non-voting members and must be free to attend all sessions of the DSMB/DMC including closed and executive sessions. The designated NCORP Research Base Statistician, or his or her designee, will also be a non-voting member of the DSMB/DMC.

The DSMB/DMC may be constituted fully by individuals who are not members of the NCORP Research Base. Alternatively, the DSMB/DMC may have voting members who are also members of the NCORP Research Base; however, the majority of the voting DSMB/DMC members cannot be affiliated with the NCORP Research Base and voting quorums for a DSMB/DMC meeting require that the majority of voting members not belong to the NCORP Research Base. NCORP Research Base members who are members of the DSMB/DMC must see themselves as primarily representing patient interests and not the interests of the NCORP Research Base or designated NCORP Research Base PI. Members of the study team or the leadership of the scientific research committees (e.g., Health Outcomes, Symptom Control, Cancer Control) of the NCORP Research Base conducting a study will recuse themselves from all DSMB/DMC discussions concerning that study and will not receive DSMB/DMC reports concerning that study. Additionally, the study statistician will not be a voting member of the DSMB/DMC for his/her trial.

The size of the DSMB/DMC should be limited, and it is unlikely that more than 10 people would be required to constitute a DSMB/DMC.

D. Meetings

DSMB/DMC meetings will be held at least once every six months. Each randomized clinical trial should have specified interim analysis times, although the DSMB/DMC should be apprised at each meeting of the status of all trials for which it is responsible, e.g., accrual, toxicity concerns, and the next formal monitoring date as specified in the protocol. DSMB/DMC meetings should be in person (rather than by telephone) generally, and especially when new members of the DSMB/DMC have been appointed. At

Part 4: Appendices

VIII. NCORP Program Data and Safety Monitoring Board (DSMB) Policy for Phase 3 Trials & Randomized Phase 2 Trials (also known as the Data Monitoring Committee (DMC) Policy): *Meetings*

a minimum, DSMB/DMC meetings must be held in person every 18 months, and any possible exceptions to this must be approved by NCI/DCP.

It is recommended that a written report outlining the current status of each trial to be monitored be sent to the DSMB/DMC members by the study statistician at least three weeks prior to the DSMB/DMC meeting. The Study Chair may prepare a report addressing specific toxicity concerns or other concerns about the conduct of the study. The statistician's report may contain recommendations on whether to close the study, whether to report the results, whether to continue accrual or follow-up and whether DSMB/DMC discussion is needed. In the event a study will be considered for closure due to slow accrual, the COPTRG members of the DSMB/DMC may discuss with other CTEP staff the possibility of early closure due to slow accrual. Although no confidential information would be disclosed, this would allow the COPTRG members of the DSMB/DMC to bring to the DSMB/DMC meeting any information from COPTRG concerning early closure that might be useful in the DSMB/DMC deliberations.

Major modifications to the study design not motivated by confidential outcome data or patient safety/toxicity data (e.g., increasing the sample size because of more rapid than expected accrual) must be discussed with NCI/DCP/COPTRG before being presented to the DSMB/DMC for consideration. If NCI/DCP/COPTRG is willing to approve the modifications, the NCORP Research Base may then seek DSMB/DMC approval before submitting an official amendment to DCP's Protocol and Information Office.

With respect to implementation of phase 2 decision rules in phase 2/3 designs of clinical trials, any protocol-specified phase 2 decision-rule analysis must be performed within 6 weeks from the date the required number of events are observed. If the trial follows the decision rule (i.e., continues or stops depending on whether the continuation threshold is met), then the Network Group notifies the DSMB/DMC and Chief, CIB of the status of the trial (i.e. continuing or stopping) based on the protocol-specified phase 2 decision rule. In the unlikely event that the study statistician wishes to request permission not to follow the protocol pre-specified decision rule, such a request must first be discussed with NCI/DCTD/CTEP by conference call within 2 weeks. This request (change in the design of the trial) needs to be approved by the CTEP Associate Director or his/her designee in consultation with the Chief, CIB who will notify the Network Group Operations Center in writing of NCI decision regarding the request. If NCI/DCTD/CTEP is willing to approve the request, the Network Group must then seek DSMB/DMC approval within 3 weeks before submitting an official amendment to CTEP's Protocol and Information Office to change the design of the trial regarding the phase 2 decision rule.

The review of each trial may include three parts. The first part will be an open session in which members of the study team and disease committee and NCI/DCP staff not on the DSMB/DMC may be present at the request of the DSMB/DMC to answer questions. In this part, the focus is on accrual,

Part 4: Appendices

VIII. NCORP Program Data and Safety Monitoring Board (DSMB) Policy for Phase 3 Trials & Randomized Phase 2 Trials (also known as the Data Monitoring Committee (DMC) Policy): *Recommendations*

compliance and toxicity issues, and no outcome results may be presented. Following the open session, there will be a closed session limited to DSMB/DMC members and possibly the study statistician in which outcome results will be presented either by a member of the DSMB/DMC, the designated NCORP Research Base Statistician, or the study statistician. It is generally recommended that outcome data be presented to the DSMB/DMC in an unblinded manner. However, if the NCORP Research Base desires to keep outcome data blinded (perhaps on some specific trials), then this is acceptable provided that any DSMB/DMC member request for unblinding for a trial will be honored. Following this closed session, there will be a fully closed, executive session in which the DSMB/DMC discusses outcome results, and then votes. At the executive session, those present are limited to DSMB/DMC members.

E. Recommendations

DSMB/DMC recommendations should be based upon results for the current study being monitored as well as upon data available to the DSMB/DMC from other related studies. The study committees, NCI/DCP staff, and individual DSMB/DMC members will assure that the DSMB/DMC is advised about relevant non-confidential results from other related studies that become available. It will be the responsibility of the DSMB/DMC, with advice from the study committee, to determine the extent to which this information is relevant to decisions to continue or modify the current study.

The DSMB/DMC will provide recommendations to the designated NCORP Research Base PI to change a study or to continue a study unchanged. In the event a change is recommended by the DSMB/DMC, the study statistician may send his/her written report that was prepared prior to the DSMB/DMC meeting to the designated NCORP Research Base PI, who may seek the advice, in a confidential manner, of the Study Chair, Scientific Committee Chair, and/or designated NCORP Research Base Statistician.

In the event that the DSMB/DMC recommends a study change for patient safety reasons (including early stopping for inferior therapy), the designated NCORP Research Base PI will act to implement the change as expeditiously as possible. For studies that are being closed based on a DSMB/DMC recommendation, although COPTRG pre-approval is not required, the designated NCORP Research Base PI (or his/her designee) must inform and discuss the closure of the study with the NCORP Director and Co-Director or his/her designee before disclosing the study closure to anyone. If the DSMB/DMC recommends closure of a study, the NCI/DCP Program Director member of the DSMB/DMC will provide the current 24/7 contact information for the NCORP Director and Co-Director or his/her designee.

In the unlikely situation that the designated NCORP Research Base PI does not concur with the DSMB/DMC recommendation, the designated NCORP Research Base PI must discuss his/her reasons for not accepting the DSMB/DMC recommendation with the NCORP Director. The NCORP

Part 4: Appendices

VIII. NCORP Program Data and Safety Monitoring Board (DSMB) Policy for Phase 3 Trials & Randomized Phase 2 Trials (also known as the Data Monitoring Committee (DMC) Policy): *Confidentiality* Procedures

Director will then inform the DCP Deputy Director of the recommendation of the DSMB/DMC and of the designated NCORP Research Base PI's reasons for disagreeing with the recommendation. The DCP Deputy Director, NCORP Director, and the designated NCORP Research Base PI, in consultation with the DSMB/DMC Chair, will be responsible for reaching a mutually acceptable decision about the study. Confidentiality will be maintained during these discussions, but relevant data will be shared with the designated NCORP Research Base PI, NCORP Director, DCP Deputy Director, and other parties whom they wish to involve in reaching a decision. In the exceptional circumstance that a mutually acceptable decision cannot be reached, final responsibility for a decision will rest with the DCP Deputy Director in consultation with the Director of the Division of Cancer Prevention.

In the event that the DSMB/DMC recommends a study be closed early due to slow accrual, then the recommendation of the DSMB/DMC would be processed as described in 1) above. Note: NCI/DCP/COPTRG may have additional closure policies that apply to studies with slow accrual that have not yet had formal interim efficacy analyses presented to the DSMB/DMC.

In the event that the DSMB/DMC recommends a change in a study for reasons other than either patient safety (e.g., to extend accrual because of an event rate lower than expected) or study closure due to slow accrual, the DSMB/DMC will provide to the designated NCORP Research Base PI an adequate rationale. In the absence of disagreement, the designated NCORP Research Base PI will be responsible for having an amendment prepared and submitted to DCP's Protocol and Information Office reflecting the recommendations of the DSMB/DMC and providing the rationale for the changes. (This is required even if NCI/DCP/COPTRG approval has been obtained prior to the amendment being presented to the DSMB/DMC.) NCI/DCP/COPTRG approval of the amendment will be required prior to implementation of the change, although it is anticipated that a decision to override the recommendation of the DSMB/DMC will be made only in the most exceptional circumstances. In the event that the NCORP Research Base PI disagrees with the DSMB/DMC recommendation, the recommendation would be processed as described in A) above.

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VIII. NCORP Program Data and Safety Monitoring Board (DSMB) Policy for Phase 3 Trials & Randomized Phase 2 Trials (also known as the Data Monitoring Committee (DMC) Policy): *Conflict of Interest*

F. Confidentiality Procedures

No communication of the deliberations or recommendations of the committee, either written or oral, should be made outside of the committee except as provided for in these policies and procedures. Statements of confidentiality should be signed by all DSMB/DMC members. Outcome (efficacy) results from phase 3, phase 2/3, and blinded randomized phase 2 trials are strictly confidential and must not be divulged to any non-member of the DSMB/DMC (excepting the designated NCORP Research Base PI, NCORP Director, and DCP Deputy Director as described above) without the approval of the DSMB/DMC until the recommendation to report the results are accepted and implemented.

G. Release of Results

For phase 3, phase 2/3, and blinded randomized phase 2 trials, **any** release of outcome data [either internal to the NCORP Research Base, to NCI personnel not members of the DSMB/DMC, or external (e.g., a paper presented at professional society meetings, seminars, papers, etc.)] prior to the final approval of general dissemination of results must be reviewed and recommended for approval by the DSMB/DMC to the designated NCORP Research Base PI. In general, outcome data from phase 3, phase 2/3, and blinded randomized phase 2 trials would not be routinely made available to individuals outside of the DSMB/DMC until accrual has ceased and all patients have concluded their randomized treatment. After this time point, the DSMB/DMC may recommend the release of outcome data on a confidential basis to the Study Chair for planning the preparation of manuscripts, and/or to a small group of individuals for purposes of planning future trials. The DSMB/DMC will consider special requests for information from the disease committee chair prior to that time point. The DSMB/DMC should be made aware of any communication of analysis results from phase 3, phase 2/3, and blinded randomized phase 2 trials outside of the statistical center at any time. The designated NCORP Research Base PI may not be able to accept the recommendation of the DSMB/DMC to release data for a specific trial if the NCORP Research Base and/or NCI/DCP/COPTRG has a binding agreement with a company collaborator (or other entity) that specifies data exclusivity for the trial without discussing the release with COPTRG (for NCORP Research Base trials with a COPTRG binding agreement) and/or the company or other collaborator (for NCORP Research Base studies that are under other binding agreements).

H. Conflict of Interest

Individuals invited to serve on the DSMB/DMC (voting and non-voting) will disclose to the designated NCORP Research Base PI any potential, real or perceived conflicts of interest. These will include professional interest, proprietary interest and miscellaneous interest considerations as described in the NCI/DCP/COPTRG Conflict of Interest Policy for NCORP Phase 3 Trials (formerly known as the NCI Conflict of Interest Policy for Cooperative Group Phase 3 Trials). The designated NCORP Research Base PI, with the advice of an ad-hoc committee, will review possible conflicts and determine whether there is sufficient basis to exclude the individual from serving on

Part 4: Appendices

**VIII. NCORP Program Data and Safety Monitoring Board (DSMB) Policy for Phase 3 Trials & Randomized Phase 2 Trials (also known as the Data Monitoring Committee (DMC) Policy):
NCI/DCP Oversight**

the DSMB/DMC. Potential conflicts which develop during the conduct of a trial should also be disclosed to the designated NCORP Research Base PI.

I. NCI/DCP Oversight

In order to satisfy its objectives of protecting patients, ensuring study integrity and assuring public confidence in the conduct of clinical trials, it is essential that the DSMB/DMC function in a manner that demonstrates competence, experience and independence of the NCORP Research Base, career or financial interests. If NCI/DCP determines that a DSMB/DMC for a NCORP Research Base is not functioning in this manner, it will discuss with the designated NCORP Research Base PI what changes are needed to the composition or structure of the DSMB/DMC.

Part 4: Appendices

VIII. NCORP Program Data and Safety Monitoring Board (DSMB) Policy for Phase 3 Trials & Randomized Phase 2 Trials (also known as the Data Monitoring Committee (DMC) Policy): *Table* of Membership of DSMB/DMC and Attendance at Sessions

J. Table of Membership of DSMB/DMC and Attendance at Sessions

If the DSMB/DMC has voting members who are also members of the Research Base, the majority of voting DSMB/DMC members cannot belong to the Research Base and voting quorums for a DSMB/DMC meeting require that the majority of voting members not belong to the .Research Base.

DSMB/DMC Membership Type	Open session	Closed Session	Executive Session
Voting member of DSMB/DMC	Present	Present (except if member of the study team or leadership of the disease committee for the study under consideration)	Present (except if member of the study team or leadership of the disease committee for the study under consideration)
NCI/DCP (non-voting) member of DSMB/DMC	Present	Present	Present
Study statistician	Present	Present	Absent
Designated Research Base Statistician (non-voting)	Present	Present	Present (except if study statistician for the study under consideration, in which case, the Designated Research Base Statistician can name another statistician from the Research Base as his/her non-voting designee for the executive session)
Designated Principal Investigator or any member of the executive leadership	Present (if he/she desires)	Absent	Absent

IX. Common Budget Outline – Suggested Format

										Consortium/ Contractual	
<i>Heading for All Direct Costs (except for per case management funding)</i>	FTEs	Salaries & Wages	Fringe	Consultants	Equipment	Supplies	Travel	Alterations/ Renovations	Other	Indirect	TOTAL

INFRASTRUCTURE COSTS

A. Group Leadership

1. Group Chair and Vice Chairs	Salary, fringe, travel and consortium/contractual indirect costs for Group Chair and any Vice or Deputy Chairs
[include all Multiple PI(s)/PD(s)]	
2. Executive Medical Officers	Salary, fringe, travel and consortium/contractual indirect costs for physicians who have oversight responsibilities for scientific activities

SUBTOTAL - GROUP LEADERSHIP

B. Scientific Leadership

1. Scientific Committee Leadership	Salary, fringe, travel and consortium/contractual indirect costs for Chairs, Vice and Deputy Chairs, Subcommittee Chairs
2. Administrative Committee Leadership	Salary, fringe, travel and consortium/contractual indirect costs for Chairs, Vice and Deputy Chairs, Subcommittee Chairs
3. Protocol Chairs	Salary, fringe, travel and consortium/contractual indirect costs or fixed payments for protocol chairs

SUBTOTAL - SCIENTIFIC LEADERSHIP

C. Group Administration

1. General Administration	Salary, fringe, office costs, travel and consortium/contractual indirect costs for administrative management, Chair's Office, if applicable, and meeting support
2. Finance/Contracting	Salary, fringe and consortium/contractual indirect costs for finance and contracting staff
3. IT Support	Salary, fringe, consortium/contractual indirect costs or other costs for administration IT support
4. Rent	Rental costs paid for Research Base space from direct dollars

SUBTOTAL - GROUP ADMINISTRATION

Part 4: Appendices

IX. Common Budget Outline – Suggested Format: *Table of Membership of DSMB/DMC and Attendance at Sessions*

										Consortium/Contractual	
<i>Heading for All Direct Costs (except for per case management funding)</i>	FTEs	Salaries & Wages	Fringe	Consultants	Equipment	Supplies	Travel	Alterations/Renovations	Other	Indirect	TOTAL

D. Trial Operations

1. Protocol Development Management	Salary, fringe, travel and consortium/contractual indirect costs for staff to develop, prepare, revise and manage protocols										
2. Regulatory	Salary, fringe, travel and consortium/contractual indirect costs for staff to administer IRB and other regulatory paperwork										
3. Audits (RESTRICTED FUNDING)	Salary, fringe, travel, consortium/contractual indirect and/or consultant costs for staff to conduct and manage audits and associated quality assurance activities										

SUBTOTAL - TRIAL OPERATIONS

E. Statistics & Data Management

1. Overall Leadership	Salary, fringe, travel and consortium/contractual indirect costs for combined statistics and data management leadership (where applicable) and their support staff										
2. Data Operations	Salary, fringe and consortium/contractual indirect costs for data management leadership, data coordinators and support personnel plus supplies and services										
3. Statistics and Bioinformatics	Salary, fringe, travel and consortium/contractual indirect costs for statistical leadership, statisticians, bioinformaticists and support personnel plus supplies and services										
4. Information Systems	Salary, fringe and consortium/contractual indirect costs for information systems leadership, applications development, database and IT support staff, equipment, software, etc.										
5. Trial Data Sets for Data Sharing (RESTRICTED FUNDING)	Salary, fringe and consortium/contractual indirect costs for statistical and data management support for creation and coordination of data sets for data sharing										

SUBTOTAL - STATISTICS & DATA MANAGEMENT

F. Scientific Services

Part 4: Appendices
: Table of Membership of DSMB/DMC and Attendance at Sessions

1. Scientific/Clinical Reviews	Salary, fringe, travel, consortium/contractual indirect, & consultant costs for toxicity, pathology, and symptom management assessment tool review and any other clinical/scientific reviews
2. Tissue Banks Coordination	Salary, fringe, travel, consortium/contractual indirect, consultant and other costs for coordination with the Tissue Bank(s) for the Research Base
3. DSMB/DMC Support (RESTRICTED FUNDING)	Salary, fringe, travel, consortium/contractual indirect and supply or other costs for outcomes, correlative studies or other scientific services
4. Other Scientific Support Services	Salary, fringe, travel, consortium/contractual indirect and supply or other costs for administration/management of DSMB/DMCs for Research Base

SUBTOTAL - SCIENTIFIC SERVICES

SUBTOTAL – INFRASTRUCTURE COSTS

PER CASE MANAGEMENT FUNDING COSTS (RESTRICTED FUNDING)

1. Molecular Screening	Estimated # of patients enrolled from institutional members in project period year who undergo molecular screening with informed consent as part of a study but who do not subsequently undergo the study intervention and/or randomization because of the screening results
2. Basic/Pilot Intervention	Estimated # of patients from institutional members in project period year randomized and/or placed on cancer prevention, control and screening/post-treatment surveillance trials
3. Health Related Quality of Life	Estimated # of patients from institutional members in project period year randomized and/or placed on health related quality of life studies
4. Biospecimen Collection	Estimated # of patients from institutional members in project period year who provide biospecimens

SUBTOTAL -PER CASE MANAGEMENT FUNDING

TOTAL - ACCRUAL COSTS & DIRECT COSTS

Part 4: Appendices

X. Accrual Input by Member Institution/Sites for NCORP Research Base Budget Requests for New Applications: ***Table of Membership of DSMB/DMC and Attendance at Sessions***

X. Accrual Input by Member Institution/Sites for NCORP Research Base Budget Requests for New Applications

The NCORP Research Base applicants must submit the breakdown of the accrual they anticipates from each of their member institutions/sites to all NCORP trials over the planned project period that was used as input to generate their budget requests in the budget section of their applications. A suggested format for a table to provide this information is provided below.

For the Research Base applicant, these tables will reflect accrual from all member sites to all NCORP trials – both trials led by the Research Base as well as accrual credited to it but for trials led by other Research Bases, if applicable.

**NCORP Key Component for Application:
Research Base - Application #1**

Institution Name	NCI Institution Code (if applicable)	Membership Type	Type Per Case Management Funding *	# Patients for Per Case Funding in Category				
				Year 1	Year 2	Year 3	Year 4	Year 5
University of WWW	WW000	Main Member	Basic Intervention	30	30	30	30	30
			Pilot Studies	5	5	5	5	5
			Health-Related Quality of Life	5	5	5	5	5
			Molecular Screening	5	5	5	5	5
			Total	45	45	45	45	45
			Biospecimen	20	20	20	20	20
Cancer Center - XXX	XX000	Affiliate of University of WWW	Basic Intervention	10	10	10	10	10
			Pilot Studies	5	5	5	5	5
			Health-Related Quality of Life	5	5	5	5	5
			Molecular Screening	5	5	5	5	5
			Total	25	25	25	25	25
			Biospecimen	5	5	5	5	5

Part 4: Appendices

X. Accrual Input by Member Institution/Sites for NCORP Research Base Budget Requests for New Applications: ***Table of Membership of DSMB/DMC and Attendance at Sessions***

University – YYY	YY000	Main Member	Basic Intervention	40	40	40	40	40
			Pilot Studies	10	10	10	10	10
			Health-Related Quality of Life	10	10	10	10	10
			Molecular Screening	5	5	5	5	5
			Total	65	65	65	65	65
			Biospecimen	10	10	10	10	10
Hospital- ZZZ	ZZ000	Affiliate of University YYY	Basic Intervention	5	5	5	5	5
			Pilot Studies	5	5	5	5	5
			Health-Related Quality of Life	5	5	5	5	5
			Molecular Screening	5	5	5	5	5
			Total	20	20	20	20	20
			Biospecimen	5	5	5	5	5